



## Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 17-40-AO

**DATE:** July 28, 2017

**TO:** State Survey Agency Directors

**FROM:** Director  
Survey and Certification Group

**SUBJECT:** FY 2016 Report to Congress (RTC): Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program

### Memorandum Summary

**Annual Report to Congress:** The 2016 annual RTC details the review, validation, and oversight of the FY 2015 activities of the approved AOs Medicare accreditation programs as well as the CLIA Validation Program.

- Section 1875(b) of the Social Security Act (the Act) requires the Centers for Medicare & Medicaid Services (CMS) to submit an annual report to Congress on its oversight of national AOs and their CMS-approved accreditation programs.
- Section 353(e)(3) of the Public Health Service Act (PHSA) requires CMS to submit an annual report of the CLIA validation program results.

### Background

The Social Security Act, Section 1875(b) requires a performance evaluation of each CMS-approved Accreditation Organization (AO) to verify that accredited provider entities demonstrate compliance with the Medicare Conditions of Participation (CoPs). The Clinical Laboratory Improvement Amendments of 1988 (CLIA), under Section 353 of the Public Health Service Act, requires that any laboratory performing testing on human specimens for health purposes, must meet the requirements established by HHS and have in effect an applicable certificate. The CMS annual Report to Congress (RTC) details the review, validation, and oversight of the AOs Medicare accreditation programs as well as those under CLIA.

State Agency surveyors conduct the validation surveys that are the basis for the analysis in the RTC. We appreciate the tremendous work of the State surveyors that has made it possible for CMS to fulfill its AO oversight responsibilities and complete the annual report to Congress.

Currently, CMS has approved accreditation programs for the following Medicare facility types: hospitals, psychiatric hospitals, critical access hospitals (CAHs), home health agencies (HHAs), hospices, ambulatory surgery centers (ASCs), outpatient physical therapy and speech-language pathology services (OPTs), and rural health clinics (RHCs). There are currently nine CMS approved Medicare accreditation organizations (AO) identified in the report:

- Accreditation Association for Ambulatory Health Care (AAAHC)
- Accreditation Commission for Health Care, Inc. (ACHC)
- American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
- American Osteopathic Association / Healthcare Facilities Accreditation Program (AOA/HFAP)
- Community Health Accreditation Program (CHAP)
- Center for Improvement in healthcare (CIHQ)
- DNV GL – Healthcare (DNV GL)
- The Compliance Team (TCT)
- The Joint Commission (JC)

There are currently another seven AOs approved under CLIA, which are:

- AABB
- American Association for Laboratory Accreditation (A2LA)
- American Osteopathic Association / Healthcare Facilities Accreditation Program (AOA/HFAP)
- American Society for Histocompatibility and Immunogenetics (ASHI)
- COLA
- College of American Pathologists (CAP)
- The Joint Commission (TJC)

**Effective Date:** Immediately. This report should be communicated with appropriate survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/  
David Wright

Attachment: Review of Medicare's Program for Oversight of Accrediting Organizations and the Clinical Laboratory Improvement Validation Program Fiscal 2016

cc: Survey and Certification Regional Office Management

# **REVIEW OF MEDICARE'S PROGRAM FOR OVERSIGHT OF ACCREDITING ORGANIZATIONS AND THE CLINICAL LABORATORY IMPROVEMENT VALIDATION PROGRAM**

**FISCAL YEAR 2016**



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## **Review of Medicare's Program for Oversight of Accrediting Organizations**

### **Introduction**

Health care facilities must demonstrate compliance with the Medicare conditions of participation (CoPs), conditions for coverage (CfCs), or conditions for certification (depending on the type of facility) to be eligible to receive Medicare reimbursement. Section 1865 of the Social Security Act (the Act) allows health care facilities that are “provider entities”<sup>1</sup> to demonstrate this compliance through accreditation by a Centers for Medicare & Medicaid Services (CMS)-approved accreditation program of a private, national Accrediting Organization (AO).<sup>2</sup> AOs may voluntarily submit provider- and supplier-specific accreditation programs intended to demonstrate compliance with the applicable Medicare standards for CMS review and approval. AOs charge fees to facilities that seek their accreditation. Generally, AOs offer facilities at least two accreditation options: accreditation alone, or accreditation under a CMS-approved program for the purpose of participating in Medicare. CMS reviews and provides oversight only for those accreditation programs submitted by an AO requesting to have the program recognized as a Medicare accreditation program. Accordingly, this report addresses AO activity only as it relates to CMS-approved Medicare accreditation programs.

CMS has responsibility for oversight and approval of AO accreditation programs used for Medicare certification purposes, and for ensuring that providers or suppliers that are accredited under an approved AO accreditation program meet the quality and patient safety standards required by the Medicare conditions.<sup>3,4</sup> A thorough review of each Medicare accreditation program voluntarily submitted by an AO is conducted by CMS, including a review of the equivalency to the Medicare standards of its accreditation requirements, survey processes and procedures, training, oversight of provider entities, and enforcement. Also reviewed are the qualifications of the surveyors, staff, and the AO’s financial status. Upon approval, any provider

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<sup>1</sup> Section 1865(a)(4) of the Act defines “provider entity” to include a provider of services, supplier, facility, clinic, agency, or laboratory. Section 1861(d) defines a “supplier” to mean a physician or other practitioner, a facility or other entity other than a provider. Section 1861(u) defines a “provider” to mean a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency or hospice program. Note that “provider entities” do not include advanced diagnostic imaging (ADI) or durable medical equipment (DME) suppliers, which are required to be accredited under Section 1834 of the Act. Oversight of ADI and DME accreditation programs are administered separately by CMS and not subject to the Section 1875 reporting requirements.

<sup>2</sup> Accreditation for provider entities in accordance with Section 1865 is voluntary and not required for Medicare participation. Accreditation by a CMS-approved national AO’s Medicare accreditation program is an alternative to being subject to assessment of compliance by the applicable State Survey Agency.

<sup>3</sup> CoPs apply to providers; CfCs apply to suppliers; and Conditions for Certification apply to rural health clinics. In this report, the term “facility” is used to cover all types of institutional health care providers which require certification in order to participate in Medicare and “Medicare conditions” and is used to cover CoPs, CfCs, and Conditions for Certification.

<sup>4</sup> The Social Security Act mandates the establishment of minimum health and safety standards that must be met by most providers and suppliers participating in the Medicare and Medicaid programs. These standards are found in Title 42 of the Code of Federal Regulations for each applicable provider/supplier type. The intention of the health and safety CoPs is to stipulate that each patient receives safe care. This often includes providing protection to the patient’s emotional health and safety as well as physical safety.

or supplier accredited by the AO's approved program could be "deemed" by CMS to have met the applicable Medicare conditions and are referred to as having deemed status.<sup>5</sup>

Pursuant to Section 1875(b) of the Act, the Secretary shall make a continuing study of the national accreditation bodies under section 1865(a), and transmit to the Congress annually a report concerning the operation and oversight of all CMS-approved AO Medicare accreditation programs. CMS has implemented a comprehensive approach to the review and approval of an AO's Medicare accreditation program and its ongoing oversight of AO activities. The primary goal of this review is to ensure that the AO's standards meet or exceed the Medicare conditions for each program type and that the organization has the capacity to adequately administer the program and provide ongoing oversight of facilities it accredits.

Currently, CMS has approved accreditation programs under 42 CFR Part 488 for the following facility types: hospitals, psychiatric hospitals, critical access hospitals (CAHs), home health agencies (HHAs), hospices, ambulatory surgery centers (ASCs), outpatient physical therapy and speech-language pathology services (OPTs), and rural health clinics (RHCs).<sup>6</sup> CMS maintains a comprehensive AO Medicare accreditation oversight program and continually strives to strengthen and enhance its ongoing oversight. The program includes:

Deeming application review – CMS rigorously reviews each Medicare accreditation program submitted by an AO initially and then periodically thereafter to determine whether the AO can adequately ensure that facilities comply with Medicare requirements;

Ongoing review – CMS evaluates the performance of each CMS-approved accreditation program on an ongoing basis through performance, comparability, and accreditation program reviews;

Electronic reporting systems – CMS builds, implements and updates electronic systems for AO reporting on activities related to deemed facilities;

Performance measurement – CMS develops and implements performance measures which reflect each AO's compliance with administrative reporting requirements;

Validation survey program – CMS has expanded efforts across a growing number of AO programs and types of facilities to measure the effectiveness of the AO survey process in identifying areas of serious non-compliance with Medicare conditions. In the validation program, CMS conducts a survey of a facility within 60 days of an AO survey and compares the findings of the two surveys to evaluate the adequacy of the AO survey process<sup>7</sup>; and

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<sup>5</sup> In accordance with section 1865 of the Act, 42 CFR §§488.5(a)(4)(i) states that AOs may award accreditation under a CMS-approved Medicare accreditation program for three years. The AOs will re-survey every accredited provider through unannounced surveys, no later than 36 months after the prior accreditation effective date.

<sup>6</sup>Note that other types of facilities may also participate in Medicare via an approved accreditation program, but to date, no AO has sought and received approval for any of these additional non-listed facility types. CMS also accredits suppliers of DMEPOS and the technical component of Advanced Diagnostic Imaging under other accreditation statutes.

<sup>7</sup> State standard survey frequencies for all provider types is addressed in the CMS' Mission and Priority Document (MPD) tier system. The State standard survey frequencies are resource driven and depend on the CMS annual

Education – CMS conducts ongoing education for AO staff that includes, but is not limited to, quarterly conference calls, an annual on-site training for all AOs with approved programs at CMS, provision of an AO resource manual, as well as availability of CMS surveyor training opportunities.

## **Overview**

This report reviews AO activities in fiscal year (FY) 2015 (October 1, 2014 – September 30, 2015), compares this activity to past years, and outlines the current CMS oversight of approved Medicare accreditation programs organized in the following sections:

### **Section 1 – CMS-Approval of Medicare Accreditation Programs**

The process used for CMS approval and renewal of AO Medicare accreditation programs; the types of CMS reviews and decisions; the number of reviews that were performed and decisions made since FY 2009; the current AOs with approved Medicare accreditation programs; and the most recent CMS approval or review status for each AO Medicare accreditation program.

### **Section 2 – Scope of Accrediting Organization Medicare Accreditation Programs**

The current number of deemed status and non-deemed Medicare-certified facilities by program type, the growth in deemed status facilities within the Medicare program since FY 2008, and the overall Medicare accreditation survey activities of each AO in FY 2015, including the number of initial and renewal accreditation surveys performed and the number of facilities denied versus the actual number of facilities which should have been reported as denied.

### **Section 3 – Accrediting Organization Performance Measures**

The AO reporting requirements and CMS' methods for collecting AO quarterly data on Medicare accreditation program activities and deemed facilities; the FY 2015 AO performance measures and the results for each AO; and comparison of FYs 2014 and 2015 performance measure results.

### **Section 4 – Validation of Accrediting Organization Surveys**

The AO Validation Program, the disparity rate for each program type nationally and by AO, and the number of representative sample validation surveys that have been performed for hospital and non-hospital facilities since FY 2007. The section also describes the comparative analysis process conducted for the 60-day validation surveys completed to assess the ability of each AO Program to evaluate and ensure compliance with the applicable Medicare conditions. The validation performance results for FYs 2012–2015 are presented by facility type for each AO. The FY 2015 AO and State Agency (SA) condition-level citations for each facility type are presented and compared. For hospital accreditation programs, validation performance results provide separate comparisons for short-term acute care and long-term care hospitals (LTCHs).

### **Section 5 – Baseline Analysis – Life Safety Code and Health & Safety Disparity Rates**

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funding level and specific criteria. Typically, State survey frequency is between 3-5 years (no more than 6 years) based on the provider type, tier priority, the number of specific providers in the state and the budget.

The most frequently disparate CoPs, Life Safety Code (LSC) and Health and Safety disparity rates, and an overall depiction of the disparity rates for individual AOs by program type, the limitations surrounding the disparity rates, and conclusions and recommendations for decreasing the disparity rates.

**Section 6 – Centers for Medicare & Medicaid Services Improvements**

CMS executed and improved program management and oversight activities for FY 2015.

**Section 7 – Clinical Laboratory Improvement Amendments Validation Program**

Clinical Laboratory Improvement Amendments (CLIA) legislative authority and mandate, validation reviews, and evaluation of AO performance.

**Appendix A – Performance Measures**

Table 1 compares the performance measure results by AO for comparable FYs 2014–2015 performance measures discussed in Section 3.

**Appendix B – Baseline Analysis – Life Safety Code and Health & Safety Disparity Rates**

Detailed FY 2015 LSC and Health and Safety statistics for each program type and AO as discussed in Section 6.

**Appendix C – Life Safety Code Category Definitions**

LSC terminology and definitions.

## **SECTION 1: CMS-Approval of Medicare Accreditation Programs**

### **Application and Renewal Process**

#### Approval of a National Accrediting Organization's Medicare Accreditation Program

The process for CMS approval of a national AO's Medicare accreditation program is voluntary and, therefore, applicant-driven. In order to gain approval of an accreditation program for Medicare deemed status purposes, an AO must demonstrate the ability to effectively evaluate a facility using accreditation standards which meet or exceed the applicable Medicare conditions, as well as survey processes that are comparable to those outlined in the State Operations Manual (SOM). Among other things, the SOM contains CMS' policy, interpretation of regulations, and instructions to SAs for conducting survey activities on behalf of CMS. Section 1865(a)(2) of the Act requires that CMS base its decision to approve or deny an AO's Medicare accreditation program application after considering the following factors:

- Program requirements for the accreditation program to meet or exceed Medicare requirements;
- Survey procedures are comparable to those of Medicare as outlined in the SOM;
- Ability to provide adequate resources for conducting surveys;
- Capacity to furnish information for use by CMS in enforcement activities;
- Monitoring procedures for providers or suppliers identified as being out of compliance with conditions or requirements; and
- Ability to provide the necessary data for validation surveys to CMS.

Section 1865(a)(3)(A) of the Act further requires that CMS publish a proposed notice in the *Federal Register* identifying the national AO making the request, the nature of the request, and provide at least a 30-day public comment period.. This notice must be published within 60 days of receipt of an AO's complete application requesting approval of a Medicare accreditation program. CMS has 210 days from receipt of a complete application to publish a *Federal Register* notice of approval or denial of the request.

The regulations at 42 CFR § 488.5 set forth the detailed requirements that an AO must satisfy in order to receive and maintain CMS recognition and approval of a Medicare accreditation program. This section also details the procedures CMS follows in reviewing AO applications.

Renewal applications are subject to the same criteria and scrutiny as initial applications for approval of an AO's Medicare accreditation program. Approval of an AO's Medicare accreditation program is for a specified time period, with a six-year maximum. Initial applications are generally provided for a four-year term of approval. This allows CMS to conduct a comprehensive review and evaluation of the renewal application within a shorter period of time to ensure that the accreditation program continues to meet CMS requirements. Some AOs are given approval on a conditional basis, while CMS reviews and monitors the accreditation program during a probationary period to determine if the program continues to meet or exceed Medicare requirements.

The application and renewal process provides the opportunity for a comprehensive evaluation of an AO's Medicare accreditation program performance. This process includes the AO's ability to ensure compliance with Medicare conditions for deemed status facilities, and the ability to comply with CMS' administrative requirements that facilitate ongoing oversight of the AO's CMS-approved accreditation program(s). The CMS evaluation process includes, but is not limited to, the following components:

- On-site observations are conducted to ensure that the accreditation program is fully implemented and operational as described in the written application:
  - Corporate on-site review; and
  - Survey observation.
- Comprehensive review of AO accreditation standards to ensure that the AO standards meet or exceed those of Medicare.
- Comprehensive review of the AO's:
  - Policies and procedures to ensure comparability with those of CMS;
  - Adequacy of resources to perform required surveys to ensure comparability with those of CMS;
  - Survey processes and enforcement to ensure comparability with those of CMS;
  - Surveyor evaluation and training to ensure comparability with those of CMS;
  - Electronic data to ensure the AO has the capacity to provide CMS with the necessary facility demographic, survey-related, deficiency, adverse action and accreditation decision data, etc.; and
  - AO financial status to ensure organizational solvency and ability to support operations.

#### Focused Reviews of Accrediting Organization Medicare Accreditation Programs

CMS performs focused reviews in the following areas:

- Standards and Survey Process Reviews: Once approved, any subsequent changes in the AO's Medicare accreditation program standards or survey process must also be reviewed and approved by CMS prior to implementation by the AO, to ensure that the program continues to meet or exceed Medicare requirements or remains comparable to Medicare survey processes and policies. Such reviews are conducted in accordance with 42 CFR § 488.5(a)(18) and 42 CFR § 488.5(a)(19).
- Issue Review and Resolution: AOs must demonstrate that their standards and review processes meet or exceed all applicable conditions of Section 1865 of the Act. CMS works with AOs to resolve issues when they are identified during the approval period.
- Performance Review: CMS reviews AO performance on an ongoing basis in accordance with Section 1875(b) of the Act. This includes, but is not limited to, review of the AO's survey activity, analysis of validation surveys, and review of the AO's continued fulfillment of the requirements at 42 CFR § 488.5.

Table 1 below summarizes the initial, renewal, and other reviews conducted by CMS.

**Table 1**  
**Centers for Medicare & Medicaid Services Review**  
**of Accrediting Organization Medicare Accreditation Programs**  
**Fiscal Years 2009-2015**

Type of Review and CMS Decision	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015
<b>Initial Applications</b>							
• Decision: Full approval	1	1	3	1	1	1	0
• Decision: Denied	0	0	0	0	0	0	0
• Incomplete application	0	0	0	2	0	0	1
• Application withdrawn	1	2	1	1	1	0	0
<b>Renewal Applications</b>							
• Decision: Full approval	6	1	0	3	6	4	6
• Decision: Denied	0	0	0	0	0	0	0
• Decision: Conditional approval	1	2	0	0	0	0	0
• Decision: Final approval removing conditional status	1	2	0	0	0	0	0
<b>Total Reviews of Initial and Renewal Applications</b>	<b>10</b>	<b>8</b>	<b>4</b>	<b>7</b>	<b>8</b>	<b>5</b>	<b>7</b>
<b>Focused Reviews</b>							
• Standards review	4	15	18	20	3	25	12
• Survey process review	4	12	10	5	0	1	5
• Issue review and resolution	*	*	44	22	41	11	3
• Performance review	1	2	3	3	0	4	3
<b>Total Focused Reviews</b>	<b>9</b>	<b>29</b>	<b>75</b>	<b>50</b>	<b>44</b>	<b>41</b>	<b>23</b>

\*Data was not collected for these issues during this timeframe.

From FY 2009 through FY 2015, CMS completed 49 reviews of renewal and initial applications (which included approvals published in the *Federal Register* as well as initial applications withdrawn by the AO prior to publication). In this same timeframe, CMS completed 271 focused reviews. In total, 320 comprehensive reviews were completed.

### Approved Accrediting Organization Medicare Accreditation Programs

CMS reviews and approves separately, each type of provider or supplier Medicare accreditation program for which an AO seeks CMS approval. AOs currently have CMS approval for eight provider/supplier program types: hospital, psychiatric hospital, CAH, HHA, hospice, ASC, OPT, and RHC. As of September 30, 2015, there were nine national AOs with 21 approved Medicare accreditation programs. (See Tables 2 and 3.)

**Table 2**  
**Accrediting Organizations with Approved Medicare Accreditation Programs**  
**Fiscal Year 2015**

AO Acronym	Description
AAAASF	American Association for Accreditation of Ambulatory Surgery Facilities, Inc.
AAAHC	Accreditation Association for Ambulatory Health Care, Inc.
ACHC	Accreditation Commission for Health Care
AOA/HFAP	American Osteopathic Association/Healthcare Facilities Accreditation Program
CHAP	Community Health Accreditation Partner
CIHQ	Center for Improvement in Healthcare Quality
DNV GL*	DNV GL-Healthcare
TCT	The Compliance Team
TJC	The Joint Commission

\*Formerly, Det Norske Veritas Healthcare, Inc. (DNVHC)

**Table 3**  
**Approved Medicare Accreditation Programs by Accrediting Organization**  
**Fiscal Year 2015**

AO	Hospital	Psych Hospital	CAH	HHA	Hospice	ASC	OPT	RHC	Total
AAAASF						X	X	X	3
AAAHC						X			1
ACHC				X	X				2
AOA/HFAP	X		X			X			3
CHAP				X	X				2
CIHQ	X								1
DNV GL	X		X						2
TCT								X	1
TJC	X	X	X	X	X	X			6
Total	4	1	3	3	3	4	1	2	21

The number of CMS-approved Medicare accreditation programs has grown steadily over the past several years resulting in 21 approved programs in FY 2015.

## Approval of Medicare Accreditation Programs

### **American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF)**

#### Ambulatory Surgery Center

AAAASF's ASC Medicare accreditation program was initially approved December 2, 1998. AAAASF's current term of approval is effective November 27, 2012 through November 27, 2018. The final notice announcing this decision was published in the *Federal Register* (77 FR 70446) (November 26, 2012), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2012-11-26/pdf/2012-28640.pdf>.

#### Outpatient Physical Therapy and Speech-Language Pathology Services

AAAASF's OPT Medicare accreditation program was initially approved April 22, 2011. AAAASF's current term of approval is effective April 22, 2015 through April 22, 2019. The final notice announcing this decision was published in the *Federal Register* (80 FR 21244) (April 17, 2015), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2015-04-17/pdf/2015-08917.pdf>.

#### Rural Health Clinic

AAAASF's RHC Medicare accreditation program was initially approved March 23, 2012. AAAASF's RHC Medicare accreditation program was granted a four-year term of approval effective March 23, 2016 through March 23, 2022. The final notice was published in the *Federal Register* (81 FR 9481)(February 25, 2016), and can be accessed at <https://www.gpo.gov/fdsys/pkg/FR-2016-02-25/pdf/2016-04092.pdf>.

#### Performance Review:

In response to significant changes in the AO's corporate structure, an on-site corporate visit was conducted in October 2013. Based on the extent and serious nature of the corporate on-site findings, CMS opened a deeming authority review for AAAASF's CMS-approved ASC, OPT, and RHC accreditation programs.

In accordance with the previous version of CMS regulations at §§488.8(f)(2) and 488.8(f)(3)(i), CMS provided AAAASF 18 months to correct identified areas of non-compliance and adopt comparable requirements. CMS completed its formal performance review in June 2015, and determined that AAAASF fully addressed and resolved all concerns regarding regulatory deficiencies, organizational policies, and clinical oversight of accredited facilities.

### **Accreditation Association for Ambulatory Health Care, Inc. (AAAHC)**

#### Ambulatory Surgery Center

AAAHC's ASC Medicare accreditation program was initially approved December 19, 1996.

AAAHC's current term of approval is effective December 20, 2012 through December 20, 2018. The final notice announcing this decision was published in the *Federal Register* (77 FR 70783) (November 27, 2012), and can be accessed at <https://www.gpo.gov/fdsys/pkg/FR-2012-11-27/pdf/2012-28728.pdf>.

### **Accreditation Commission for Health Care (ACHC)**

#### Home Health Agency

ACHC's HHA Medicare accreditation program was initially approved February 24, 2006. ACHC's current term of approval is effective February 24, 2015 through February 24, 2021. The final notice announcing this decision was published in the *Federal Register* (80 FR 2708) (January 20, 2015), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2015-01-20/pdf/2015-00699.pdf>.

#### Hospice

ACHC's hospice Medicare accreditation program was initially approved November 27, 2009. ACHC's current term of approval is effective November 27, 2013 through November 27, 2019. The final notice announcing this decision was published in the *Federal Register* (78 FR 66364) (November 5, 2013), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2013-11-05/pdf/2013-26374.pdf>.

### **American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)**

#### Hospital

AOA/HFAP has had an approved hospital Medicare accreditation program since 1965. Although its hospital program is mentioned by name in the Act, it is also explicitly subject to the Secretary's review and approval. AOA/HFAP's current term of approval is effective September 25, 2013 through September 25, 2019. The final notice announcing this decision was published in the *Federal Register* (78 FR 53149) (August 28, 2013), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2013-08-28/pdf/2013-21008.pdf>.

#### Critical Access Hospital

AOA/HFAP's CAH Medicare accreditation program was initially approved December 27, 2001. AOA/HFAP's current term of approval is effective December 27, 2013 through December 27, 2019. The final notice announcing this decision was published in the *Federal Register* (78 FR 71619) (November 29, 2013), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2013-11-29/pdf/2013-28521.pdf>.

#### Ambulatory Surgery Center

AOA/HFAP's ASC Medicare accreditation program was initially approved January 30, 2003.

AOA/HFAP's current term of approval is effective October 23, 2013 through October 23, 2017. The final notice announcing this approval was published in the *Federal Register* (77 FR 59616) (September 28, 2012), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2012-09-28/pdf/2012-23996.pdf>.

### **Community Health Accreditation Partner (CHAP)**

#### Home Health Agency

CHAP's HHA Medicare accreditation program was initially approved August 27, 1992. CHAP's current term of approval is effective March 31, 2012 through March 31, 2018. The final notice announcing this decision was published in the *Federal Register* (77 FR 17072) (March 23, 2012), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2012-03-23/pdf/2012-6598.pdf>.

#### Hospice

CHAP's hospice Medicare accreditation program was initially approved April 20, 1999. CHAP's current term of approval is effective November 20, 2012 through November 20, 2018. The final notice announcing this decision was published in the *Federal Register* (77 FR 64344) (October 19, 2012), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2012-10-19/pdf/2012-25467.pdf>.

### **Center for Improvement in Healthcare Quality (CIHQ)**

#### Hospital

CIHQ's hospital Medicare accreditation program was initially approved for a four-year term effective July 26, 2013 through July 26, 2017. The final notice announcing this approval was published in the *Federal Register* (78 FR 45231) (July 26, 2013), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-18014.pdf>.

### **DNV GL-Healthcare (DNV GL)**

#### Hospital

DNV GL's hospital Medicare accreditation program was initially approved September 29, 2008. DNV GL's current term of approval is effective September 26, 2012 through September 26, 2018. The final notice announcing this decision was published in the *Federal Register* (77 FR 51537) (August 24, 2012), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2012-08-24/pdf/2012-20199.pdf>.

#### Critical Access Hospital

DNV GL's CAH Medicare accreditation program was initially approved December 23, 2010. DNV GL's current term of approval is effective December 23, 2014 through December 23, 2020.

The final notice announcing this decision was published in the *Federal Register* (79 FR 69482) (November 21, 2014), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2014-11-21/pdf/2014-27576.pdf>.

### **The Compliance Team (TCT)**

#### Rural Health Clinics

TCT's RHC Medicare accreditation program was initially approved for a four-year term effective July 18, 2014 through July 18, 2018. The final notice announcing this approval was published in the *Federal Register* (79 FR 42019) (July 18, 2014), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2014-07-18/pdf/2014-16735.pdf>.

### **The Joint Commission (TJC)**

#### Hospital

TJC's hospital Medicare accreditation program was initially approved July 15, 2010. Prior to July 15, 2010, TJC's hospital accreditation program had statutory status and did not require CMS review and approval. TJC's current term of approval is effective July 15, 2014 through July 15, 2020. The final notice announcing this decision was published in the *Federal Register* (79 FR 36524) (June 27, 2014), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2014-06-27/pdf/2014-15103.pdf>.

#### Psychiatric Hospital

TJC's psychiatric hospital Medicare accreditation program was initially approved for a four-year period effective February 25, 2011 through February 25, 2015. TJC's current term of approval is effective February 25, 2015 through February 25, 2019. The final notice announcing this decision was published in the *Federal Register* (80 FR 9466) (February 23, 2015), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2015-02-23/pdf/2015-03559.pdf>.

#### Performance Review:

Based on the serious nature of the corporate on-site findings during a November 3–5, 2015 corporate on-site visit and validation survey disparity rates for FYs 2013, 2014, and 2015, an accreditation program review was opened for TJC's CMS-approved psychiatric hospital accreditation program on December 17, 2015.

In accordance with CMS regulation §488.8(c), TJC was given six months to correct identified areas of non-compliance and adopt comparable requirements. The six-month review period ended June 14, 2016. At that time, it was determined that TJC failed to satisfactorily demonstrate compliance or implement and sustain improvements based on the requirements outlined in TJC's plans of correction (POCs) dated January 15, 2016, March 30, 2016, and June 15, 2016.

In accordance with CMS regulation §488.8(c)(3), CMS placed TJC's psychiatric hospital accreditation program on probation for six months. TJC has an opportunity to implement the approved corrective actions during the probationary period which ended on December 17, 2016. CMS has 60 calendar days from the end of the probationary period to conduct a corporate on-site visit and issue written determination, including supportive findings, as to whether or not TJC's CMS-approved psychiatric hospital accreditation program continues to meet the Medicare requirements.

#### Critical Access Hospital

TJC's CAH Medicare accreditation program was initially approved November 21, 2002. TJC's current term of approval is effective November 21, 2011 through November 21, 2017. The final notice announcing this decision was published in the *Federal Register* (76 FR 59134) (September 23, 2011), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2011-09-23/pdf/2011-24496.pdf>.

#### Home Health Agency

TJC's HHA Medicare accreditation program was initially approved September 28, 1993. TJC's current term of approval is effective March 31, 2014 through March 31, 2020. The final notice announcing this decision was published in the *Federal Register* (79 FR 14049) (March 12, 2014), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2014-03-12/pdf/2014-05328.pdf>.

#### Hospice

TJC's hospice Medicare accreditation program was initially approved June 18, 1999. TJC's current term of approval is effective June 18, 2015 through June 18, 2021. The final notice announcing this decision was published in the *Federal Register* (80 FR 29714) (May 22, 2015), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2015-05-22/pdf/2015-12524.pdf>.

#### Ambulatory Surgery Center

TJC's ASC Medicare accreditation program was initially approved December 19, 1996. TJC's current term of approval is effective December 20, 2014 through December 20, 2020. The final notice announcing this decision was published in the *Federal Register* (79 FR 69486) (November 21, 2014), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2014-11-21/pdf/2014-27577.pdf>.

## **SECTION 2: Scope of Accrediting Organization Medicare Accreditation Programs**

### **Medicare-Participating Facilities by Program Type:**

In FY 2015, AOs were responsible for assuring compliance with Medicare conditions for 40 percent of all Medicare-participating facilities in the eight program types for which there was an approved AO program. (See Table 4 and Graph 1.)

**Table 4**  
**Deemed & Non-Deemed Medicare-Participating Facilities**  
**Program Types with a Medicare Accreditation Program Option**  
**Fiscal Year 2015**

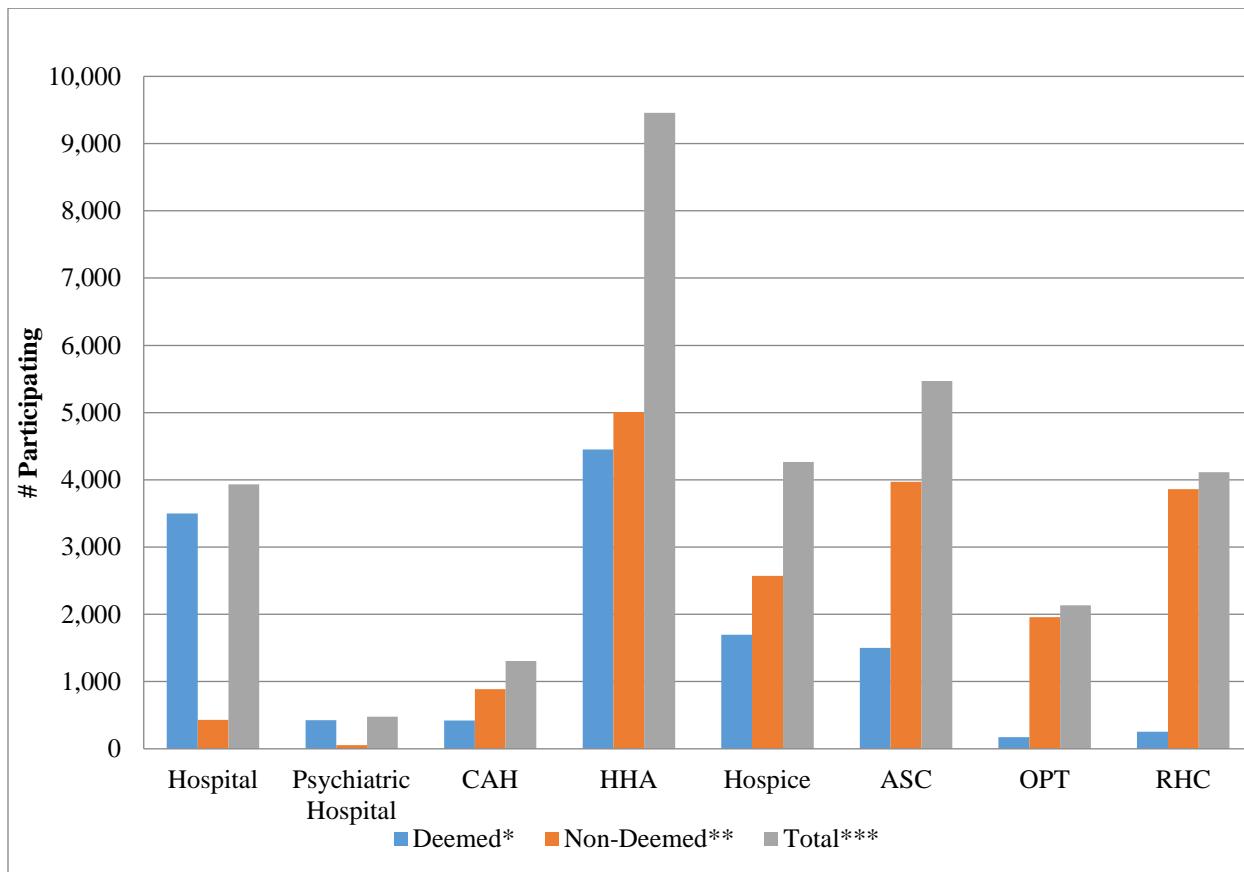
Program Type	Deemed* (percentage)	Non-Deemed** (percentage)	Total***
Hospital	3,500 (89)	432 (11)	3,932
Psychiatric Hospital	424 (89)	53 (11)	477
CAH	420 (32)	887 (68)	1,307
HHA	4,450 (47)	5,008 (53)	9,458
Hospice	1,694 (40)	2,573 (60)	4,267
ASC	1,499 (27)	3,973 (73)	5,472
OPT	175 (8)	1,957 (92)	2,132
RHC	253 (6)	3,862 (94)	4,115
<b>Total</b>	<b>12,415 (40)</b>	<b>18,745 (60)</b>	<b>31,160</b>

\*As reported by AOs in Accrediting Organization System for Storing User Recorded Experiences (ASSURE).

\*\*Surveyed by an SA for compliance with Medicare conditions.

\*\*\*As reported by CMS Data Team 1/13/2016.

**Graph 1**  
**Deemed & Non-Deemed Medicare-Participating Facilities**  
**Program Types with a Medicare Accreditation Program Option**  
**Fiscal Year 2015**



\*As reported by AOs in Accrediting Organization System for Storing User Recorded Experiences (ASSURE).

\*\*Surveyed by an SA for compliance with Medicare conditions.

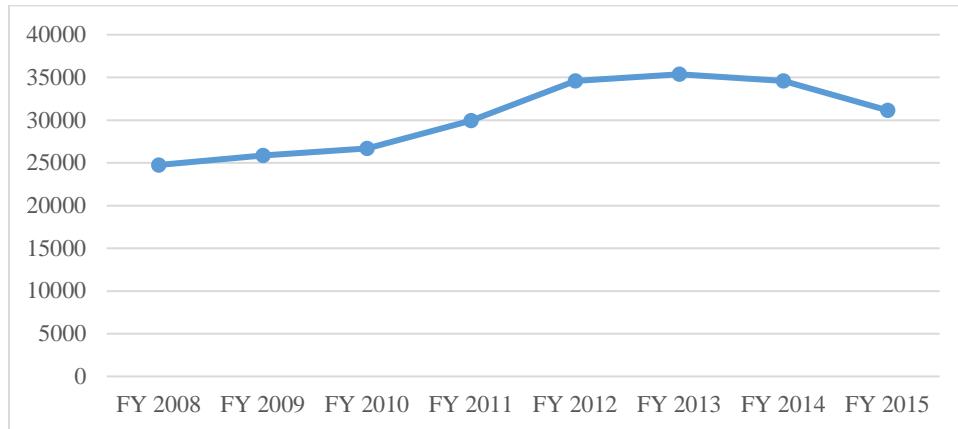
\*\*\*As reported by CMS Data Team 1/13/2016.

In FY 2015, the AOs with CMS-approved Medicare accreditation programs were responsible for monitoring compliance with health and safety standards for varying percentages of the total number of Medicare-participating facilities for each program type. This percentage ranges from a high of 89 percent for hospitals and psychiatric hospitals to a low of 6 percent for RHCs. The hospital category has historically had the largest percentage of facilities participating in Medicare via deemed status until this year.

### Growth in Medicare Deemed Facilities

The total number of Medicare-participating health care facilities across all program types has increased 26 percent from 24,752 in FY 2008 to 31,160 in FY 2015. Since FY 2008, the majority of those newly participating facilities with an accreditation option, enrolled and became certified in the Medicare program via accreditation from a CMS-approved Medicare accreditation program and deemed status. (See Graph 2.)

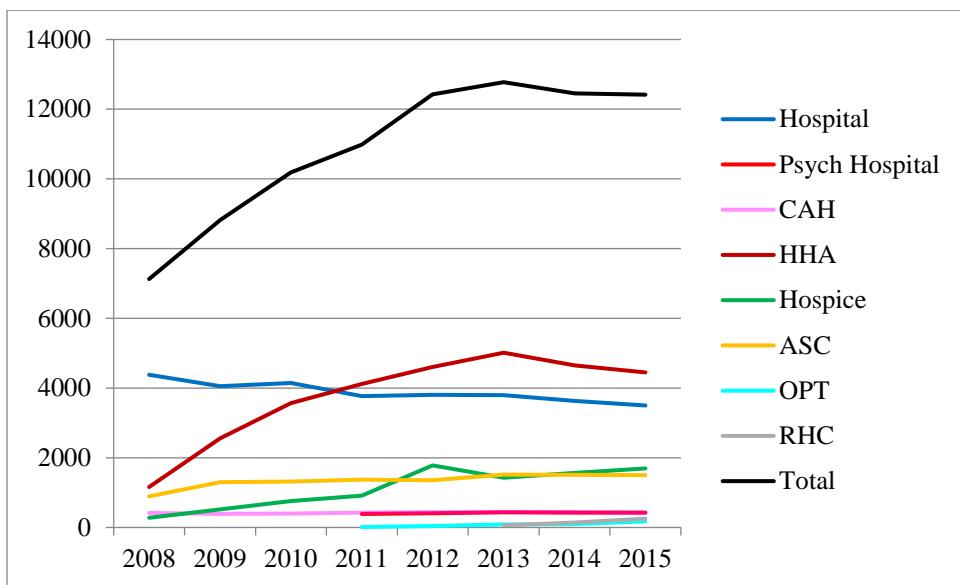
**Graph 2**  
**Medicare-Participating Health Care Facilities**  
**Fiscal Years 2008-2015**



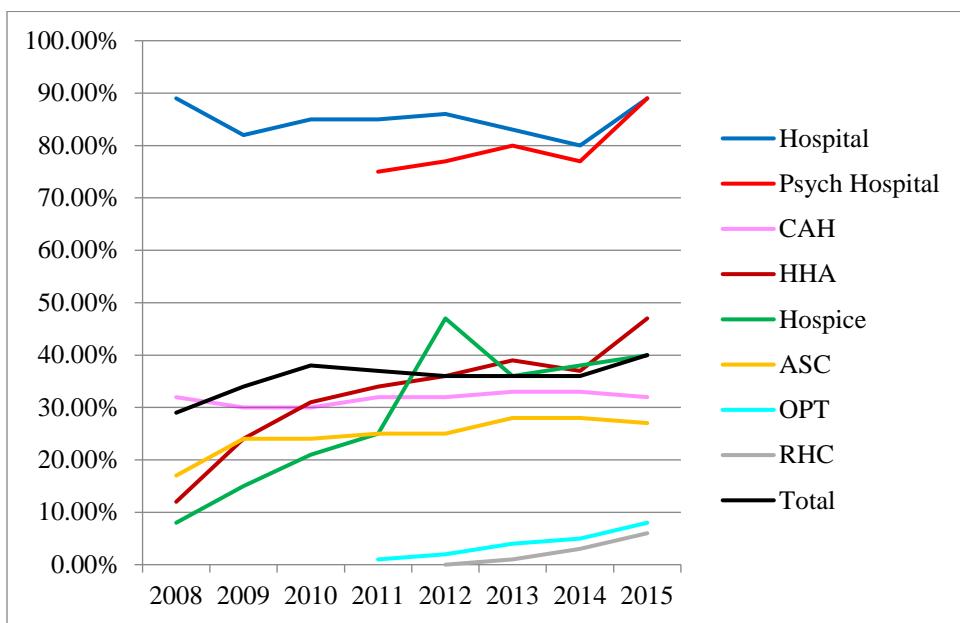
The growth in the number of deemed facilities is likely attributable, in part, to CMS' workload priorities for SAs. The long-standing CMS policy for SAs has been that initial surveys for newly enrolling facilities with an approved accreditation option have a lower priority as compared to statutorily mandated recertification surveys of participating nursing homes, HHAs and hospices, validation surveys, complaint investigations, other recertification surveys, and initial surveys of new applicants for which no accreditation option exists. As a result, an increasing number of facilities seeking initial Medicare participation have used CMS-approved Medicare accreditation programs to demonstrate their compliance with Medicare requirements to facilitate a faster enrollment and certification process. The decline from FY 2013 to FY 2015 seen in graph 2 is likely attributed to the consolidation of health care facilities within the industry.

Graphs 3 and 4 below show the number of facilities certified each year by CMS by virtue of a CMS-recognized Medicare accreditation program, and the percentage of all Medicare-certified facilities that these deemed facilities represent. These graphs represent the eight program types for which there is currently more than one-year of data.

**Graph 3**  
**Number of Deemed Facilities by Program Type**  
**Fiscal Years 2008-2015**



**Graph 4**  
**Deemed Facilities as Percentage of Medicare-Participating Facilities by Program Type**  
**Fiscal Years 2008-2015**



- **Total:** Since the introduction of the original AO Medicare accreditation programs (hospitals, CAHs, HHAs, hospices, and ASCs), three more types of accreditation programs have been approved since FY 2008. The first OPT and psychiatric hospital Medicare accreditation

programs were approved in FY 2011<sup>5</sup>. The first RHC Medicare accreditation program was approved in FY 2012. Although the number of Medicare-participating facilities increased 26 percent, the growth in deemed facilities during that same period was much larger.

- The number of facilities participating in Medicare via deemed status increased from 7,128 in FY 2008 to 12,415 in FY 2015, a 74 percent increase.
  - The number of facilities participating in Medicare via deemed status decreased from 12,451 in FY 2014 to 12,415 in FY 2015, a less than one percent decrease.
  - The SAs continue to survey and monitor the majority of Medicare-participating facilities. However, the proportion of facilities participating in Medicare via their accreditation from a CMS-approved Medicare accreditation program and deemed status has grown from 29 percent to 40 percent.
- **Hospital:** The number of Medicare-participating hospitals was largely unchanged between FYs 2008 and 2015. The hospital and psychiatric hospital programs are the only categories in which the majority of facilities participate in Medicare by virtue of accreditation under an approved Medicare accreditation program.
    - The number of deemed hospitals decreased from 4,381 in FY 2008 to 3,500 in FY 2015, a reduction of 20 percent. (Please note: this decrease in percentage is adjusted based on the separate reporting of 424 deemed psychiatric hospitals.)
    - The number of deemed hospitals decreased from 3,629 in FY 2014 to 3,500 in FY 2015, a reduction of four percent.
    - The proportion of all Medicare-participating hospitals that were deemed remained at 89 percent in FY 2015.
  - **Psychiatric Hospital:** The number of Medicare-certified psychiatric hospitals decreased from 516 in FY 2011 to 477 in FY 2015, an eight percent decrease.
    - The number of deemed psychiatric hospitals increased from 388 in FY 2011 to 424 in FY 2015, a nine percent increase.
    - The number of deemed psychiatric hospitals decreased from 425 in FY 2014 to 424 in FY 2015, a reduction of less than one percent.
    - The proportion of all Medicare- participating psychiatric hospitals which were deemed increased from 75 percent in FY 2011 to 89 percent in FY 2015.
  - **CAH:** The number of Medicare-certified CAHs were essentially unchanged with 1,310 in FY 2008 to 1,307 in FY 2015.
    - The number of deemed CAHs increased slightly from 415 in FY 2008 to 420 in FY 2015, a one percent increase.
    - The number of deemed CAHs decreased from 439 in FY 2014 to 420 in FY 2015, a four percent decrease.
    - The proportion of all Medicare-certified deemed CAHs remained at 32 percent in FY 2015.
  - **HHA:** The number of Medicare-certified HHAs decreased from 9,893 in FY 2008 to 9,458 in FY 2015, a four percent decrease.

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<sup>5</sup> Prior to FY 2011, the number of psychiatric hospitals participating in Medicare through a CMS-approved accreditation program were included in the total number of hospitals.

- The number of deemed HHAs increased from 1,161 in FY 2008 to 4,450 in FY 2015, a 283 percent increase.
  - The number of deemed HHAs decreased from 4,652 in FY 2014 to 4,450 in FY 2015, a four percent decrease.
  - The proportion of all Medicare-certified HHAs which were deemed nearly quadrupled from 12 percent in FY 2008 to 47 percent in FY 2015.
- **Hospice:** There has been significant growth in the Medicare hospice program as well. The number of Medicare-certified hospices increased from 3,388 in FY 2008 to 4,267 in FY 2015, a 26 percent increase. There has also been corresponding significant growth in the number and proportion of deemed hospices.
  - The number of deemed hospices increased from 278 in FY 2008 to 1,694 in FY 2015, a 509 percent increase.
  - The number of deemed hospices increased from 1,562 in FY 2014 to 1,694 in FY 2015, an eight percent increase.
  - The proportion of all Medicare-certified hospices which were deemed increased five-fold from 8 percent in FY 2008 to 40 percent in FY 2015.
- **ASC:** The number of Medicare-certified ASCs increased from 5,217 in FY 2008 to 5,472 in FY 2015, a five percent increase.
  - The number of deemed ASCs increased significantly from 893 in FY 2008 to 1,499 in FY 2015, a 68 percent increase.
  - The number of deemed ASCs decreased from 1,507 in FY 2014 to 1,499 in FY 2015, a less than one percent decrease.
  - The proportion of all Medicare-certified ASCs which were deemed increased from 17 percent in FY 2008 to 27 percent in FY 2015.
- **OPT:** The number of Medicare-certified OPTs decreased from 2,471 in FY 2011 to 2,132 in FY 2015, a 14 percent decrease.
  - The number of deemed OPTs increased from 13 in FY 2011 to 175 in FY 2015, a 1,246 percent increase. This large percentage increase is due to the relative recent availability of an accreditation option for OPTs. CMS-approved the first Medicare OPT accreditation program April 2011. Therefore, there was a small number of deemed OPTs in FY 2011.
  - The number of deemed OPTs increased from 97 in FY 2014 to 175 in FY 2015, an 80 percent increase.
  - The proportion of all Medicare-certified OPTs which were deemed increased from one percent in FY 2011 to eight percent in FY 2015.
- **RHC:** The number of Medicare-certified RHCs remained essentially flat from 4,108 in FY 2012 to 4,115 in FY 2015.
  - The number of deemed RHCs increased from 3 in FY 2012 to 253 in FY 2015, an 8,333 percent increase. This large percentage increase is due to the relative recent availability of an accreditation option for RHCs. CMS approved the first Medicare RHC

accreditation program May 2012. Therefore, there was an extremely low number of deemed RHCs in FY 2012.

- The number of deemed RHCs increased from 140 in FY 2014 to 253 in FY 2015, an 81 percent increase.
- The proportion of all Medicare-certified RHCs which were deemed increased from less than one percent in FY 2012 to six percent in FY 2015.

### **Medicare Accreditation Program Survey Activity**

An AO with a CMS-recognized Medicare accreditation program is responsible for evaluating a facility through an on-site survey to determine whether the facility complies with the health care quality and patient safety standards required by the Medicare conditions. The evaluation performed by the AO includes, but is not limited to, observation and review of the following: care processes in the facility; the physical environment (PE) including compliance with the Life Safety Code (LSC) when applicable; administrative and patient medical records; and staff qualifications. The AO performs an initial survey for a facility that is being reviewed by the AO for the first time. Initial surveys include surveys of facilities that are seeking initial Medicare certification as well as those facilities currently participating in Medicare and previously overseen by an SA or another AO. The AO may award accreditation under a CMS-approved Medicare accreditation program for up to three years. A renewal survey must be completed prior to the expiration date of the facility's Medicare accreditation to ensure that the facility remains in compliance with CMS requirements.

In FY 2015, the AOs reported having performed 1,618 initial surveys and 3,874 renewal surveys. The total number of deemed status facilities in FY 2015 was 12,434. The total number of facilities denied was 308. The actual total number of deemed facilities which should have been reported as denied, according to CMS policy, was 345. (See Table 5.)

It is important to note, when looking at the number of denials, that many factors may influence and affect the data reported. CMS has identified numerous surveys that should have technically been reported as a denial, but through the reporting process, were erroneously reported as full accreditations. Those denials are identified in Table 5 below. This identified issue has been addressed within the scope of the AO performance measures. CMS has reviewed the issue with the AOs demonstrating difficulty in accurately reporting denials and the issue has been improving throughout the FY 2016 period.

In addition, facilities seeking initial deemed status with an AO must be found to be in compliance with *all* conditions through the on-site survey activity. “Condition-level” deficiencies are the most serious type of deficiency cited, indicating a provider or supplier is not in compliance with an entire CoP. A “standard-level” deficiency means that the provider may be out of compliance with one aspect of the regulations, but is considered less serious than a condition-level finding. If a facility is found to have condition-level non-compliance on an initial survey, the facility must be denied accreditation. A second deemed status survey must be conducted once the facility has submitted an acceptable POC and corrected all deficiencies. Through the process of reviewing survey reports and findings made by the AOs, CMS has identified that in some cases, an AO may not have cited certain findings at the appropriate level

(e.g., deficiencies were cited at a “standard” level, instead of at the “condition” level). This issue may also create a “false low” in the reporting of denials. (See Table 5.) In identifying these issues, CMS is actively involved in reinforcing the decision-making process related to the appropriate level of citation with the AOs. Citing deficiencies at the appropriate level, is an essential component to assuring the health and safety of patients receiving care in Medicare facilities.

**Table 5**  
**Total Number of Deemed Facilities**  
**Initial Surveys and Renewal Surveys**  
**by Accrediting Organization (AO) Accreditation Program**  
**Fiscal Year 2015**

Program Type/ AOs	Total Deemed Facilities	Initial Surveys	Renewal Surveys	Denials
<b>Hospital</b>				
AOA/HFAP	141	3	40	2
CIHQ	23	20	0**	4
DNV GL	277	34	80	1 (8*)
TJC	3,074	53	1,085	3 (5*)
<b>Hospital Total</b>	<b>3,515</b>	<b>110</b>	<b>1,205</b>	<b>10 (19*)</b>
<b>Psychiatric Hospital</b>				
TJC	424	31	123	0 (2*)
<b>Psychiatric Hospital Total</b>	<b>424</b>	<b>31</b>	<b>123</b>	<b>0 (2*)</b>
<b>CAH</b>				
AOA/HFAP	28	1	7	0
DNV GL	73	16	8	0 (6*)
TJC	320	17	132	2 (4*)
<b>CAH Total</b>	<b>421</b>	<b>34</b>	<b>147</b>	<b>2 (10*)</b>
<b>HHA</b>				
ACHC	662	123	166	49
CHAP	2,070	291	665	76
TJC	1,719	139	592	46 (54*)
<b>HHA Total</b>	<b>4,451</b>	<b>553</b>	<b>1,423</b>	<b>171 (179*)</b>
<b>Hospice</b>				
ACHC	154	54	24	14
CHAP	755	146	252	46
TJC	786	163	187	14 (19*)
<b>Hospice Total</b>	<b>1,695</b>	<b>363</b>	<b>463</b>	<b>74 (79*)</b>
<b>ASC</b>				
AAAASF	158	40	48	17
AAAHC	773	108	259	10
AOA/HFAP	24	6	7	1
TJC	545	100	139	5 (10*)

Program Type/ AOs	Total Deemed Facilities	Initial Surveys	Renewal Surveys	Denials
<b>ASC Total</b>	<b>1,500</b>	<b>254</b>	<b>453</b>	<b>33 (38*)</b>
<b>OPT</b>				
AAAASF	175	108	34	8
<b>OPT Total</b>	<b>175</b>	<b>108</b>	<b>34</b>	<b>8</b>
<b>RHC</b>				
AAAASF	195	99	26	6
TCT	58	66	0***	4
<b>RHC Total</b>	<b>253</b>	<b>165</b>	<b>26</b>	<b>10</b>
<b>Total</b>	<b>12,434</b>	<b>1,618</b>	<b>3,874</b>	<b>308 (345*)</b>

Source: As reported by the AOs in ASSURE.

\*The actual number of denials that should have been reported.

\*\*The CIHQ Hospital accreditation program received initial approval in FY 2013. Therefore, no renewal surveys were due to be conducted in FY 2015.

\*\*\*TCT RHC accreditation program received initial approval in FY 2014. Therefore, no renewal surveys were due to be conducted in FY 2015.

Note: The total number of deemed facilities on this table includes 19 facilities that are dually accredited; therefore, the total number of deemed facilities listed in Table 4 is less than this total.

## **SECTION 3: Accrediting Organization Performance Measures**

### **Accrediting Organization Reporting Requirements**

A major focus of CMS' ongoing work with each AO is monitoring and improving the AO's ability to provide CMS with complete, timely, and accurate information regarding deemed status facilities, as required at 42 CFR §488.5(a)(4)(viii). It is important that AOs and CMS be able to accurately determine a facility's Medicare accreditation status on an ongoing basis. This information is vital for CMS to be able to identify which facilities participate in Medicare via their deemed status and are, therefore, subject to AO versus SA oversight. Additionally, when an AO makes an adverse Medicare accreditation program decision based on a facility's failure to satisfy the AO's health and safety standards or LSC requirements, it is imperative that CMS be notified promptly in order to take appropriate follow-up enforcement action. It is also essential for CMS to have information concerning upcoming AO survey schedules to effectively implement the validation program. To this end, AOs must submit the following to CMS:

- Monthly survey schedules which document the surveys that were completed for the previous month, and those scheduled for the current and following months;
- A report of all data pertaining to all Medicare accreditation and enforcement activity for each month;
- Facility notification letters for all Medicare accreditation program actions and any follow-up communication associated with those facility notification letters; and
- Responses to any formal correspondence from CMS.

In 2008, CMS directed the development of an electronic data collection tool that would enable the AOs to provide CMS with demographic and survey activity information for deemed facilities. The database, ASSURE, provides a method to collect, analyze, and manage data regarding deemed facilities. In 2013, the system moved to a web-based version. ASSURE centralizes data capture and reporting; supports the integration of AO data into the existing Quality Improvement Evaluation System (QIES) infrastructure for network access; ensures that data conforms to the national data structures framework; and allows for Certification and Survey Provider Enhanced Reports (CASPER) authentication and reporting.

CMS employs several methods to facilitate obtaining this information. In addition to providing AOs access to and implementing ongoing improvements to ASSURE, CMS provides the AOs with:

- Information on the essential elements that should be included in an AO facility notification letter regarding a facility's Medicare accreditation status, to facilitate AO communication with CMS;
- Dedicated Central Office (CO) and Regional Office (RO) electronic mailboxes for AO submission of copies of facility notification letters concerning their Medicare accreditation program status; and
- Comparative analysis and feedback on the deemed facility data contained in ASSURE. This includes whether the facilities in ASSURE could be matched to certified facilities in CMS' national Medicare certification database.

## **Accrediting Organization Performance Measures and Scoring**

In FY 2009, CMS instituted performance measures for AOs. These measures are reviewed and updated annually. These measures provide CMS with a method of assessing each AO's ability to provide CMS with timely, accurate and complete information regarding the various aspects of facility survey and monitoring activities. They also enable CMS to determine the current Medicare accreditation status of certified health care facilities.

Each performance measure is scored on a quarterly basis. For survey schedule measures and Web-ASSURE import file uploads, the quarterly score is calculated based on monthly scores. Annual scores are the average of all four quarterly scores. Measures are scored as a percentage of correct submissions for a specific month/quarter.

### **FY 2015 Accrediting Organization Performance Measures**

In FY 2015, AOs were scored on their performance on 15 measures in 4 key performance focus areas: ASSURE Database; Facility Notification Letters; Survey Schedule; and Formal Correspondence. (See Table 6.)

**Table 6**  
**Accrediting Organization (AO) Performance Measures**  
**Fiscal Year 2015**

#### **ASSURE Database:**

AOs use the ASSURE electronic database to record all AO Medicare accreditation program activity, including enforcement activity, and to submit a quarterly export file of this ASSURE data to CMS. Performance in this area was based on:

- The accuracy and completeness of deemed facility data in ASSURE as measured by:
  - The number of CMS Certification Numbers (CCNs) present (not missing more than 180 days)
- The timeliness of conducting triennial (renewal) surveys
- The facilities with condition-level findings denied on initial surveys\*
- The timeliness of uploading Web-ASSURE import files
- The no-match\*\* lists as measured by:
  - The timeliness of electronic submission of no-match data follow-up activity
  - The evidence of no-match reconciliation

#### **Facility Notification Letters:**

AOs should electronically submit facility notification letters to CMS for all Medicare accreditation program actions in CMS-approved programs. Performance in this area was based on:

- The accuracy and completeness of the letters submitted as measured by:
  - All required attachments are included

- Do not contain duplicate notices
- The notification letters contain all required information
- The data in ASSURE is being updated consistent with the letters
- The data in ASSURE is being corrected to address previous quarter CMS-identified deficiencies

#### **Survey Schedule:**

AOs should submit a monthly schedule which documents surveys completed in the past month as well as scheduled surveys for the current and next two months. Performance in this area is based on:

- The accuracy of monthly survey schedules (specifically, no instances of arrival of the SA to conduct a validation survey and being informed that the accreditation survey had not been conducted as indicated on the survey schedule)
- The timeliness of reporting changes in the survey schedule and incorporating these changes in the next survey schedule submission (and in the proper format)
- The accuracy of the data in ASSURE regarding number of surveys reported as completed for the quarter and the number of surveys actually completed each quarter

#### **Formal Correspondence:**

AOs should submit a response to formal CMS correspondence addressing issues of concern. Performance in this area was based on:

- The timely responses to formal correspondence (on or before the specified due date)

\*Initial surveys that result in condition-level findings must be denied accreditation. Before being awarded accreditation for the purpose of Medicare deemed status, a facility must demonstrate substantial compliance with the Medicare requirements. Therefore, these facilities are required to correct identified deficiencies and undergo another survey to demonstrate full compliance with all Medicare conditions and an acceptable POC for any less serious, standard-level deficiencies before an AO may grant full accreditation and make a recommendation to CMS that the facility be granted deemed status.

\*\*Records in ASSURE undergo a “matching” process on a nightly basis. This process attempts to match records within ASSURE to records held in the National Database. When the system is unable to automatically match records, these are noted as being a “no-match”.

### **Significant Changes for FY 2015 Accrediting Organization Performance Measures**

#### Retired FY 2015 Performance Measures

In FY 2015, CMS retired one of the FY 2014 performance measures in one key performance focus area.

#### **ASSURE Database:**

- Accuracy and completeness of deemed facility data in ASSURE
  - The number of pending surveys (not pending more than 180 days)

## New FY 2015 Performance Measures

CMS added two new performance measures in one key performance focus area in FY 2015.

### **Facility Notification Letters:**

- The notification letters contain all required information
- ASSURE data is updated consistent with the letters

## **Performance Measure Results**

The FY 2014 and FY 2015 performance data for all AOs is presented below in two tables. The first table, Table 7, presents results for performance measures that were monitored in FYs 2014 and 2015. A comparison is presented by FY for these measures. The second table, Table 8, presents results for performance measures specific to FY 2015, including the addition of three new measures. Therefore, the data in Table 8 cannot be directly compared to the FY 2014 performance measure results and are presented independently. Both tables present the performance measures according to the key focus areas. All results include quarterly averages utilizing standard rounding rules. The data represent the percent frequency with which the task required by the measure was performed in an accurate, timely, complete manner. A discussion of the performance measure scoring and results follows the tables.

**Table 7**  
**Performance Measure Results (Percentage) for All Accrediting Organizations Comparable Measures for Fiscal Years (FY) 2014–2015**

Performance Measure Results (Percentage) for All Accrediting Organizations Comparable Measures for FYs 2014–2015	FY 2014*	FY 2015
Number of CCNs present (not missing more than 180 days)	99	99
Timely triennial surveys**	100	100
Denied initial surveys with condition-level findings	45	81
Timely uploading of Web-ASSURE import files	98	98
Timely electronic submission of no-match data follow-up***	96	97
Evidence of no-match reconciliation***	100	100
Letters submitted with attachments	92	100
No duplicate notices submitted	100	100
AO conducted survey as reported on survey schedule	100	100
Timely submission of schedule changes and proper incorporation into the next monthly schedule	99	100
Number of surveys performed matches number reported in ASSURE	93	96
Responses to CMS on or before specified due date	89	100

\*TCT received initial approval in July 2014; therefore, TCT is not included in the FY 2014 data.

\*\*CIHQ received initial approval in July 2013 and TCT received initial approval in July 2014; therefore, neither AO had renewal surveys due in FYs 2014 or 2015.

\*\*\*CIHQ had no “no-match” records in FYs 2014 and 2015.

**Table 8**  
**Performance Measure Results (Percentage) for All Accrediting Organizations**  
**Fiscal Year (FY) 2015**  
**(Not Comparable to FY 2014 Measures)**

Performance Measure Results (Percentage) for All Accrediting Organizations FY 2015 (Not Comparable to FY 2014 Measures)	<b>FY 2015</b>
Notification letters contain all required information	96
ASSURE is updated consistent with letters	87

### **Scoring Definitions:**

- “Performed well” means a 100 percent score.
- “Substantial improvement” means improved by at least 10 percent in FY 2015 compared to the previous year.
- “Opportunity for improvement” means any score below 95 percent in FY 2015.
- “Lower score” means a decrease of at least 10 percent in FY 2015 compared to the previous year.

### **Highlights**

#### **1. ASSURE Database**

- All AOs scored 95 percent or higher for the measure “Number of CCNs present (not missing greater than 180 days)” in both FYs 2014 and 2015.
- All AOs scored 99 percent or higher for the measure “Timely triennial surveys” in both FYs 2014 and 2015 with the exception of two AOs for which no renewal surveys were due to be conducted in this timeframe.
- In FY 2014, only four AOs had sample sizes greater than five and were able to calculate a score for the measure “Denied initial surveys with conditions.” All but one AO showed opportunity for improvement, resulting in an overall lower score. In FY 2015, all of the AOs had sample sizes greater than five and all but one AO demonstrated substantial improvement with increases in scores ranging from 19 percent to 83 percent from FYs 2014 to 2015. Additionally, in FY 2015, five of the AOs performed well; however, four of the AO scores ranged from 17 percent to 83 percent, showing opportunity for improvement and impacting an overall lower score for this measure.
- In FY 2014, out of all of the AOs who use the ASSURE upload function, only one showed opportunity for improvement for the measure “Timely uploading of Web-ASSURE import files”; three of the AOs performed well on this same measure in both FYs 2014 and 2015 and all but one AO performed well in FY 2015.
- In FY 2014, the AOs performed well on the measure “Timely electronic submission of no-match data follow-up” with the exception of one AO who showed opportunity for improvement. From FYs 2014 to 2015, one AO scored lower with a 25 percent decrease for the same measure, also showing an opportunity for improvement. However, one AO substantially improved with a 25 percent increase during that same time. The remaining AOs scored 100 percent in both FYs 2014 and 2015 with the exception of one AO who

had zero “no-match” records during the FYs 2014 and 2015 reporting periods and one AO who had zero ‘no-match’ records during FY 2015. Typically, the smaller AOs have applicable records matched to a record already in ASPEN.

- All AOs performed well for the measure “Evidence of no-match reconciliation” in both FYs 2014 and 2015 with the exception of one AO who had zero “no-match” records during the FYs 2014 and 2015 reporting periods and one AO who had the same scenario in FY 2015.
- The following measures were retired at the end of FY 2015, due to sustained high performance: “Number of CCNs present (not missing greater than 180 days),” “Timely triennial surveys,” and “Timely uploading of Web-ASSURE import files.” CMS reviews the performance measure scores annually to determine which measures, if any, can be retired prior to the next FY.

## **2. Facility Notification Letters**

- In FY 2014, four of the AOs scored 100 percent for the measure “Letters Submitted with Attachments,” while three AOs showed opportunity for improvement. In FY 2015, two of the AOs showed substantial improvement, scoring 14 percent to 34 percent higher when compared to the previous year. In FY 2015, all AOs scored 100 percent for the same measure.
- In FY 2014, all but one AO scored 100 percent for the measure, “No duplicate notices submitted” and all but one AO had the necessary data to calculate the measure. In FY 2015, all AOs scored 100 percent for the same measure.
- For the new FY 2015 measure, “Letters contain all required information,” two of the AOs showed opportunity for improvement. Two of the AOs performed well, scoring 100 percent.
- For the new FY 2015 measure “ASSURE updated consistent with the letter,” six of the AOs showed opportunity for improvement with scores ranging from 76 percent to 90 percent, resulting in an overall lower score. None of the AOs performed well on this new measure.
- The following measure was retired at the end of FY 2015, due to sustained high performance: “Duplicate notices are not forwarded to CMS.” CMS reviews the performance measure scores annually to determine which measures, if any, can be retired prior to the next FY.

## **3. Survey Schedule**

- All AOs scored 100 percent for the measure, “AO conducted survey as reported on the survey schedule,” for both FYs 2014 and 2015 with the exception of one AO which did not have available information in FY 2014 to calculate this measure.
- All AOs scored 100 percent for the measure, “Timely submission of schedule changes and proper incorporation into the next monthly schedule” in FY 2014 with the exception of one AO who showed opportunity for improvement and another AO who did not have information available to calculate this measure. In FY 2015, all AOs scored 100 percent on the same measure.
- In FY 2014, five AOs showed opportunity for improvement, with scores ranging from 82 percent to 94 percent for the measure, “Number of surveys performed matches the number reported in ASSURE.” During that same time, one AO performed well, while

another AO did not have the information available to calculate the measure. In FY 2015, two AOs showed opportunity for improvement with scores of 84 percent and 87 percent respectively. Seven AOs scored 97 percent or higher for the same measure, of which three performed well. One AO substantially improved by 15 percent from the previous year.

- The following measure was retired at the end of FY 2015, due to sustained high performance: “Survey schedule changes are submitted on a weekly basis.” CMS reviews the performance measure scores annually to determine which measures, if any, can be retired prior to the next FY.

#### **4. Formal CMS Correspondence**

- In FY 2014, all but three AOs, with the exception of one AO who did not have available information to calculate the measure, achieved a 100 percent score for the measure, “Responses to CMS on or before specified due date.” Those same three AOs also showed opportunity for improvement with scores ranging from 42 percent to 94 percent. In FY 2015, all AOs scored 100 percent for this measure. Two AOs substantially improved from the previous year resulting in a higher overall score.
- Although all AOs performed well, the Formal CMS Correspondence measure was not recommended for retirement at the end of FY 2015 due to the recent history of performance scores lower than 100 percent by several of the AOs. CMS continues to work closely with AOs to improve performance in areas that need improvement as well as to maintain high levels of performance in other areas. The goal is for all AOs to consistently score at or near 100 percent on all measures to ensure that AOs are effectively managing their Medicare accreditation programs and communicating vital program information to CMS.

#### **Accrediting Organization Specific Discussion (See Appendix A)**

##### **American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF)**

For the performance measures that can be compared to FY 2014 scores, AAAASF continued to perform well on three of the six ASSURE Database performance measures, one of two Facility Notification Letters performance measures, two of three Survey Schedule performance measures, and the Formal Correspondence performance measure. While AAAASF showed substantial improvement for “denied initial surveys with condition-level findings,” they continue to have opportunity for improvement. AAAASF also showed opportunity for improvement on one of the two new FY 2015 measures, “ASSURE is updated consistent with letters.” For all measures where AAAASF demonstrated an opportunity for improvement, CMS worked with the AO to determine possible causes and provided guidance on improving future scores. In summary, AAAASF performed well on 10 of 15 measures in FY 2015.

##### **Accreditation Association for Ambulatory Health Care, Inc. (AAAHC)**

For the performance measures that can be compared to FY 2014 scores, AAAHC continued to perform well on the measures, “evidence of no-match reconciliation,” “letters submitted with attachments,” “AO conducted survey as reported on survey schedule,” “timely submission of

schedule changes and proper incorporation into the next monthly schedule,” and “responses to CMS on or before specified due date.” AAAHC didn’t have a sufficient sample size to calculate a score for the measure “denied initial surveys with condition-level findings.” AAAHC showed opportunity for improvement on 3 of the 15 comparable measures, “timely electronic submission of no-match data follow-up” for which they also had a lower score, “timely uploading of Web-ASSURE import files” and “number of surveys performed matches number reported in ASSURE.” AAAHC showed opportunity for improvement on each of the two new FY 2015 measures, “notification letters contain all required information” and “ASSURE is updated consistent with the letters.” For all measures where AAAHC demonstrated an opportunity for improvement or a lower score as compared to FY 2014, CMS worked with the AO to determine possible causes and provided guidance on improving future scores. In summary, AAAHC performed well on 7 of 15 measures.

### **Accreditation Commission for Health Care (ACHC)**

For the performance measures that can be compared to FY 2014 scores, ACHC continued to perform well on five of the six ASSURE Database performance measures, all of the Facility Notification Letters performance measures, two of three Survey Schedule performance measures and the Formal Correspondence performance measure. In summary, ACHC also performed well on two additional measures in FY 2015, “denied initial surveys with condition-level findings” and “number of surveys performed matches number reported in ASSURE”. ACHC performed well on all of the comparable FY 2015 measures. ACHC also performed well on one of the two new FY 2015 Facility Notification Letters performance measures, “notification letters contain all required information.” Overall, ACHC performed well on 14 of 15 performance measures in FY 2015.

### **American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)**

For the performance measures that can be compared to FY 2014 scores, AOA/HFAP continued to perform well in each of the performance measures found within the four key focus areas with the exception of “denied initial surveys with condition-level findings.” AOA/HFAP did not have a sufficient sample size in FY 2014 to calculate this measure, therefore, a comparison cannot be made. Overall, AOA/HFAP performed well on 13 of 15 performance measures.

### **Community Health Accreditation Partner (CHAP)**

For the performance measures that can be compared to FY 2014 scores, CHAP continued to perform well on the measures, “timely triennial surveys,” “timely electronic submission of no-match data follow-up,” “evidence of no-match reconciliation,” “no duplicate notices submitted,” and “AO conducted survey as reported on survey schedule.” In summary, CHAP performed well and showed substantial improvement on the measures “denied initial surveys with condition-level findings” and “responses to CMS on or before specified due date.” CHAP also performed well on the measures “letters submitted with attachments” and “timely submission of schedule changes and proper incorporation into the next monthly schedule.” CHAP showed opportunity for improvement on one of the two new FY 2015 measures, “ASSURE is updated consistent

with letters.” CHAP did not have any information regarding “timely uploading of Web-ASSURE import files,” as information reported in ASSURE is entered manually and not imported into the system. For all measures where CHAP demonstrated an opportunity for improvement, CMS worked with the AO to determine possible causes and provided guidance on improving future scores. Overall, CHAP performed well on 9 of 14 applicable measures.

### **Center for Improvement in Healthcare Quality (CIHQ)**

CIHQ did not have any information for the calculation of the FY 2014 comparable performance measure “timely uploading of Web-ASSURE import files,” as information reported in ASSURE is entered manually and not imported into the system. There was no information related to “timely triennial surveys,” due to the fact that they just received CMS approval in 2013, and no triennial surveys were due in FY 2015. The “timely electronic submission of no-match data follow-up” and “evidence of no-match reconciliation” also had no reportable scores due to the absence of any no-match records during the reporting year. In FY 2014, CIHQ did not have a sample size large enough to calculate the measure “denied initial surveys with condition-level findings.” CIHQ continued to perform well on the measures “number of CCNs present (not missing > 180 days),” “letters submitted with attachments,” “no duplicate notices submitted,” “AO conducted survey as reported on survey schedule,” “timely submission of schedule changes and proper incorporation into the next monthly schedule,” and “responses to CMS on or before specified due date.” In summary, CIHQ performed well on the measures “denied initial surveys with condition-level findings” and “number of surveys performed matches number reported in ASSURE” for which CIHQ showed substantial improvement. CIHQ also performed well on one of the two new FY 2015 measures “notification letters contain all required information.” CIHQ did not have any information for the calculation of the “timely uploading of Web-ASSURE import files” as information reported in ASSURE is entered manually and not imported into the system. Overall, CIHQ performed well on 10 of 11 applicable measures.

### **DNV GL-Healthcare (DNV GL)**

For the performance measures that can be compared to FY 2014 scores, DNV GL continued to perform well on 6 of the 14 applicable measures. DNV GL did not have a sufficient sample size to calculate the measure “denied initial surveys with condition-level findings.” In summary, DNV GL performed well on the measures “letters submitted with attachments” and “responses to CMS on or before specified due date” for which DNV GL also showed substantial improvement. DNV GL showed opportunity for improvement for the measure “denied initial surveys with condition-level findings” as well as one of the two new FY 2015 measures “ASSURE is updated consistent with letters.” DNV GL did not have any information for calculating a score for the measure, “timely uploading of Web-ASSURE import files,” as information reported in ASSURE is entered manually. For all measures where DNV GL demonstrated an opportunity for improvement, CMS worked with the AO to determine possible causes and provided guidance on improving future scores. Overall, DNV GL performed well on 8 of 14 applicable measures.

### **The Compliance Team (TCT)**

TCT did not have any information for the calculation of any of the FY 2014 comparable performance measures. In summary, TCT showed opportunity for improvement on the measures “denied with initial surveys with condition-level findings,” “number of surveys performed matches number reported in ASSURE,” and both of the two new FY 2015 measures “notification letters contain all required information” and “ASSURE is updated consistent with letters.” TCT did not have any information for calculating a score for the measure, “timely uploading of Web-ASSURE import files,” as information reported in ASSURE is entered manually or “timely triennial surveys.” For all measures where TCT demonstrated an opportunity for improvement, CMS worked with the AO to determine possible causes and provided guidance on improving future scores. Overall, TCT performed well on 8 of 13 applicable measures.

### **The Joint Commission (TJC)**

For the performance measures that can be compared to FY 2014 scores, TJC continues to perform well on the measures, “timely uploading of Web-ASSURE import files,” “timely electronic submission of no-match data follow-up,” “evidence of no-match reconciliation,” “no duplicate notices submitted,” “AO conducted survey as reported on survey schedule,” and “timely submission of schedule changes and proper incorporation into the next monthly schedule.” In summary, TJC performed well on the measures “responses to CMS on or before specified due date” and “letters submitted with attachments” for which TJC also showed substantial improvement. In addition, TJC showed substantial improvement, but still has opportunity for improvement for the measure “denied initial surveys with condition-level findings.” TJC showed an opportunity for improvement for one of the two new FY 2015 measures “ASSURE is updated consistent with letters.” For all measures where TJC demonstrated an opportunity for improvement or a lower score as compared to FY 2014, CMS worked with the AO to determine possible causes and provided guidance on improving future scores. Overall, TJC performed well on 8 of 15 measures.

## **SECTION 4: Validation of Accrediting Organization Surveys**

### **Accreditation Validation Program**

Section 1864(c) of the Act permits SA validation surveys of provider and supplier types deemed for Medicare participation under Section 1865(a) of the Act as a means of validating the AOs' accreditation processes. A facility certified on the basis of being "deemed" to meet the Medicare conditions based on accreditation by a CMS-approved Medicare accreditation program and recommendation for deemed status by the AO, is not subject to routine surveys by SAs to determine compliance with all applicable Medicare conditions. However, these deemed status facilities may be subject to validation surveys authorized by CMS and generally conducted by an SA.

The Accreditation Validation Program is one component of CMS oversight of AOs with approved Medicare accreditation programs, and consists of two types of validation surveys:

- Substantial allegation surveys (also called "complaint surveys") – focused surveys based on complaints which, if substantiated, could indicate serious noncompliance with one or more Medicare conditions; and
- Representative sample validation surveys – full surveys which are routinely performed for a representative sample of deemed facilities as part of the annual CMS-AO representative sample validation survey program. These surveys must be completed by the SA within 60 days of an AO full accreditation survey for the same facility. In some cases, representative sample "mid-cycle validation surveys" may be conducted independent of a preceding AO survey.

Note: The discussion in this section of the methodology for and results of CMS validation of the AOs' Medicare accreditation programs is based only upon analysis of the 60-day representative sample validation surveys.

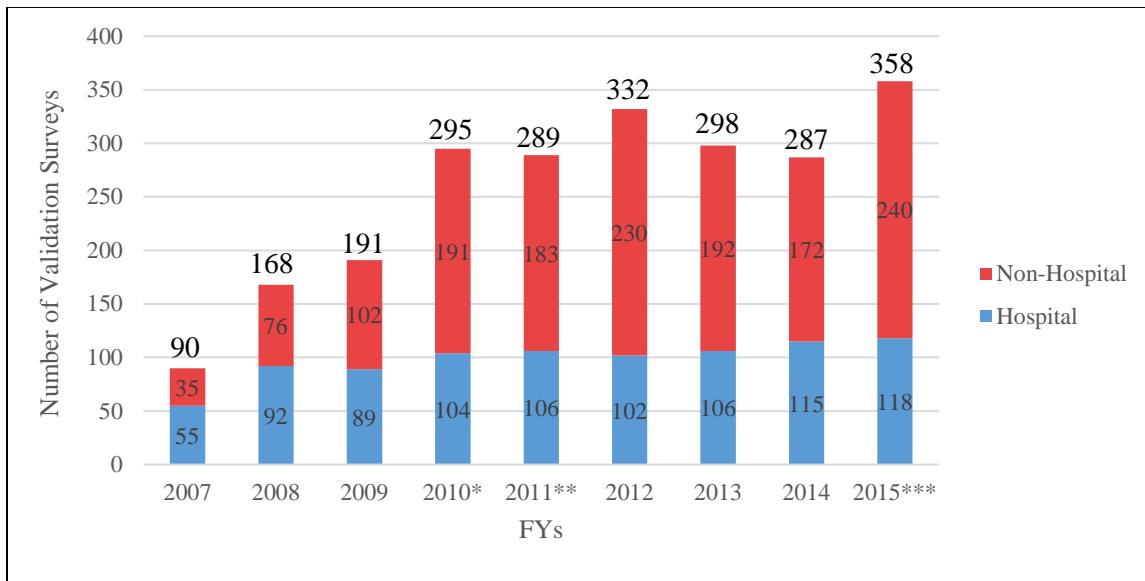
Prior to 2009, section 1875 of the Act required CMS to report to Congress annually only on TJC's hospital program.<sup>8</sup> Nevertheless, in FY 2007, CMS began conducting 60-day representative sample validation surveys for selected non-hospital facility types (CAHs, HHAs, and ASCs), in addition to those already being performed for deemed status hospitals. In FY 2010, hospice 60-day validation surveys were added, and in FY 2011, psychiatric hospital 60-day validation surveys were added. In FY 2015, CMS conducted a total of 358 representative sample 60-day validation surveys for six facility types across AOs.<sup>9</sup> This total comprised 118 hospital surveys (including 16 psychiatric hospitals) and 240 non-hospital validation surveys. (See Graph 5.)

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<sup>8</sup>Section 125(b)(4) of P.L. 110-275 (2008) revised this provision to apply to all AOs.

<sup>9</sup>In FY 2015, OPT, which includes the newly accredited TCT, and RHC providers were not part of the validation sample.

**Graph 5**  
**Number of Representative Sample Validation Surveys for**  
**Both Hospital and Non-Hospital Facilities**  
**Fiscal Years (FYs) 2007–2015**



\*In FY 2010: The non-hospital total of 191 includes 72 mid-cycle ASC validation surveys.

\*\*In FY 2011: The hospital total of 106 includes 33 mid-cycle LTCH validation surveys.

\*\*\*In FY 2015: The hospital total of 118 includes 16 psychiatric hospital validation surveys.

Since 2007, CMS has worked to strengthen oversight of AOs. From FYs 2007–2012, the number of validation surveys conducted expanded significantly as more attention and Federal resources were made available to this priority area; however, FYs 2013–2014 showed slight decreases in the amount of surveys completed. These decreases were due to decreased funding available for validation surveys subsequent to the FY 2013 budget sequestration. FYs 2014–2015 showed an increase in the amount of surveys conducted. These increases were due to the availability of additional mid-year AO validation program budget funds. The recent history of validation survey samples is as follows:

- 2007: 55 hospital and 35 non-hospital surveys totaling 90 surveys
- 2008: 92 hospital and 76 non-hospital surveys totaling 168 surveys
- 2009: 89 hospital and 102 non-hospital surveys totaling 191 surveys
- 2010: 104 hospital and 191 non-hospital surveys, including 72 ASC mid-cycle surveys, totaling 295 surveys
- 2011: 106 hospital surveys, including 33 LTCH mid-cycle surveys, and 183 non-hospital surveys totaling 289 surveys
- 2012: 102 hospital and 230 non-hospital surveys totaling 332 surveys
- 2013: 106 hospital and 192 non-hospital surveys totaling 298 surveys
- 2014: 115 hospital and 172 non-hospital surveys totaling 287 surveys
- 2015: 118 hospital and 240 non-hospital surveys totaling 358 surveys

These numbers represent a 298 percent increase in the overall number of validation surveys conducted, from 90 in FY 2007 to 358 in FY 2015. During the same time period, the number of non-hospital validation surveys conducted increased by 586 percent, from 35 surveys in FY 2007 to 240 surveys in FY 2015. The number of hospital validation surveys conducted increased by 115 percent, from 55 surveys in FY 2007 to 118 surveys in FY 2015.

## 60-Day Validation Surveys

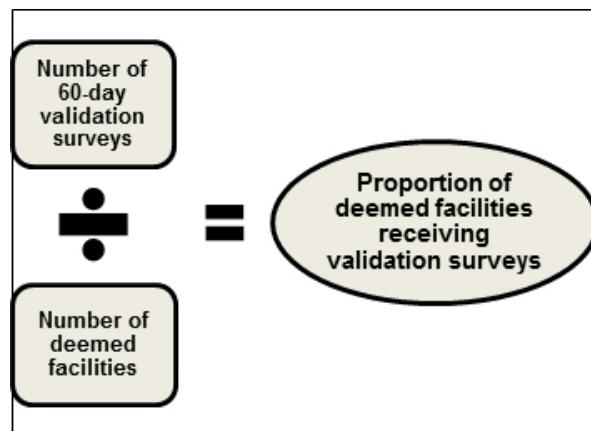
The purpose of 60-day validation surveys is to assess the AO's ability to ensure compliance with Medicare conditions. These validation surveys are on-site full surveys completed by SA surveyors no later than 60 days after the end date of an AO's Medicare accreditation program full survey. The SA performs these surveys without any knowledge of the findings of the AO's accreditation survey.

The composition of the validation sample is driven by a number of factors, including the total number of Medicare accreditation surveys scheduled by the AO and reported on monthly survey schedules furnished to CMS, the accuracy of those schedules, and individual State validation survey volume targets. CMS determines the number of validation surveys to perform for each AO based on the number of facilities the AO surveys each month, as well as the overall budgeted targets, by State and facility type, for validation surveys. CMS builds a representative national sample for individual accreditation programs.

### Proportion of Deemed Facilities Receiving Validation Surveys

The proportion of 60-day validation surveys completed for deemed facilities is calculated by dividing the number of 60-day validation surveys conducted by the total number of deemed facilities. (See Figure 1.)

**Figure 1**  
**Proportion of Deemed Facilities Receiving Validation Surveys**



The proportion of deemed facilities that received a 60-day validation survey in FY 2015 is as follows:

- **Hospitals:** Three percent of deemed hospitals received a validation survey in FY 2015 (102 validation surveys conducted out of 3,500 deemed facilities).
- **Psychiatric Hospitals:** Four percent of deemed psychiatric hospitals received a validation survey in FY 2015 (16 validation surveys conducted out of 424 deemed facilities).
- **CAHs:** Eight percent of deemed CAHs received a validation survey in FY 2015 (33 validation surveys conducted out of 420 deemed facilities).
- **HHAs:** Two percent of deemed HHAs received a survey in FY 2015 (104 validation surveys conducted out of 4,450 deemed facilities).
- **Hospices:** Two percent of deemed hospices received a validation survey in FY 2015 (34 validation surveys conducted out of 1,694 deemed facilities).
- **ASCs:** Five percent of deemed ASCs received a validation survey in FY 2015 (69 validation surveys conducted out of 1,499 deemed facilities).

## **Validation Analysis**

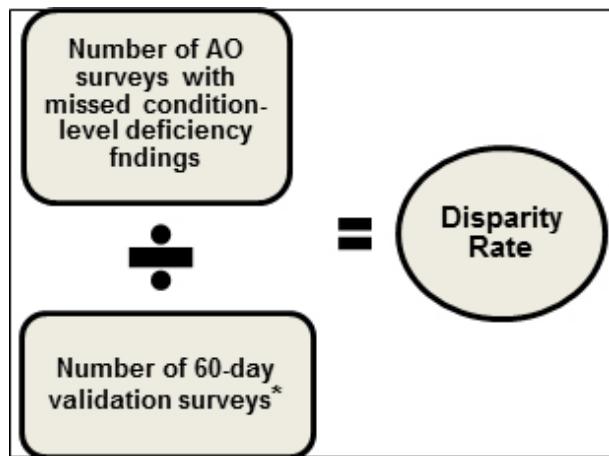
### Condition-Level Deficiencies and Disparity Rate

After the 60-day validation surveys are completed, CMS performs a validation analysis and compares the condition-level deficiencies (i.e., serious deficiencies) cited by the SA with all deficiencies cited by the AO on its Medicare accreditation survey. The goal of this validation analysis is to determine whether the AOs are able to accurately identify serious deficiencies in a facility. The premise of the analysis is that condition-level deficiencies cited by the SA during the 60-day validation survey would also have been present 60 days prior, during the AO's Medicare accreditation survey, and should also have been cited by the AO.

When the SA finds a condition-level deficiency in a deemed status facility, CMS removes its deemed status and places it under the jurisdiction of the SA until the facility comes into substantial compliance. If the facility is unable to demonstrate substantial compliance in a timely manner, the facility's participation in Medicare is terminated. If compliance is demonstrated, CMS restores the facility's deemed status and returns the facility to the AO's jurisdiction.

When the SA cites a condition-level deficiency for which the AO has cited no comparable deficiency, the deficiency is considered by CMS to have been "missed" by the AO and is a factor in determining the AO's "disparity rate" for each facility type. (See Figure 2.)

**Figure 2**  
**Disparity Rate Calculation**



\*The number of 60-day validation surveys includes the total number of 60-day validation surveys conducted regardless of whether or not the SA cited condition-level deficiencies.

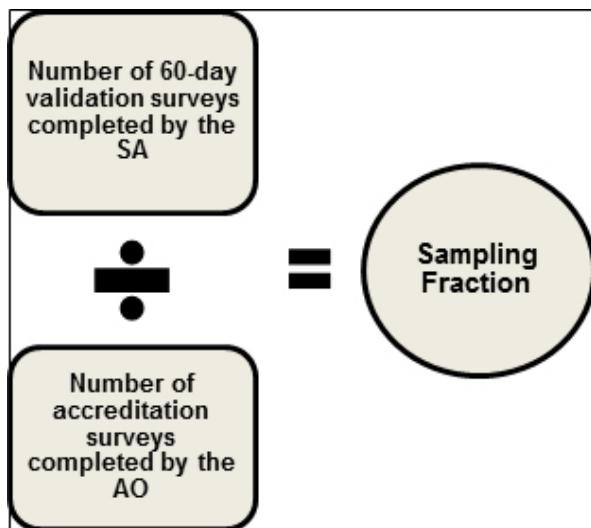
The methodology for the disparity rate is set by regulation at 42 CFR § 488.1. The numerator is the number of surveys where the AO did not cite a comparable serious (condition-level) deficiency as cited by the SA. The denominator is the total number of surveys in the 60-day representative validation sample. The result is the percentage of 60-day validation surveys where the AO did not cite a comparable serious deficiency as cited by the SA. For example, if there are 77 (60-day) validation surveys conducted, and the AO missed 12 condition-level deficiencies cited by the SA, the disparity rate would be 16 percent (12 divided by 77).

There are, however, limitations when discussing disparity rates. The disparity rate does not solely measure the AO's performance. Additionally, a high AO disparity rate does not necessarily indicate unsatisfactory performance by the AO. (See Section 5.)

#### Sampling Fraction

The sampling fraction is the proportion of AO surveys during the FY for which a representative sample 60-day validation survey was completed. (See Figure 3.)

**Figure 3**  
**Sampling Fraction Calculation**



For example, if the number of 60-day validation surveys conducted by the SA is 33 and the overall number of accreditation surveys conducted by the AO over the same time period is 638, then the sampling fraction would be 33 divided by 638 – which is five percent. CMS has worked to increase this sampling fraction for each AO and to include a minimum of five 60-day validation surveys per year for each AO program, no matter how small the program.

In summary, the *disparity rate* focuses on the number of 60-day validation surveys where the AO did not cite comparable condition-level deficiencies cited by SAs in relation to the total number of validation surveys completed by the SA. The *sampling fraction* is the proportion of 60-day validation surveys completed by the SA in relation to the number of Medicare accreditation surveys completed by the AO.

#### **Validation Performance Results: Each Facility Type**

The table below presents the results of the 60-day validation surveys for all AOs from FY 2012 through FY 2015 by facility type. (See Table 9.)

**Table 9**  
**60-Day Validation Survey Results for Each Facility Type**  
**Fiscal Years (FYs) 2012–2015**

	FY 2012	FY 2013	FY 2014	FY 2015
<b>HOSPITAL</b>				
60-Day Validation Sample Surveys	102	96	103	102
SA Surveys with Condition-Level Deficiencies	50	52	41	42

	FY 2012	FY 2013	FY 2014	FY 2015
AO Surveys with Missed Comparable Deficiencies	45	44	39	40
Disparity Rate	44%	46%	38%	39%
Sampling Fraction	.08	.07	.09	.08
<b>PSYCHIATRIC HOSPITAL</b>				
60-Day Validation Sample Surveys*	8	10	12	16
SA Surveys with Condition-Level Deficiencies	6	6	10	12
AO Surveys with Missed Comparable Deficiencies	6	6	9	11
Disparity Rate	75%	60%	75%	69%
Sampling Fraction	.05	.06	.08	.10
<b>CRITICAL ACCESS HOSPITAL</b>				
60-Day Validation Sample Surveys	33	35	27	33
SA Surveys with Condition-Level Deficiencies	15	17	16	15
AO Surveys with Missed Comparable Deficiencies	12	14	14	15
Disparity Rate	36%	40%	52%	45%
Sampling Fraction	.13	.23	.17	.18
<b>HOME HEALTH AGENCY</b>				
60-Day Validation Sample Surveys	102	80	75	104
SA Surveys with Condition-Level Deficiencies	30	15	16	23
AO Surveys with Missed Comparable Deficiencies	19	11	11	17
Disparity Rate	19%	14%	15%	16%
Sampling Fraction	.05	.04	.04	.05
<b>HOSPICE</b>				
60-Day Validation Sample Surveys	21	18	16	34
SA Surveys with Condition-Level Deficiencies	2	1	3	4
AO Surveys with Missed Comparable Deficiencies	2	1	1	3
Disparity Rate	10%	6%	6%	9%
Sampling Fraction	.04	.03	.02	.04

	FY 2012	FY 2013	FY 2014	FY 2015
<b>AMBULATORY SURGERY CENTER</b>				
60-Day Validation Sample Surveys	66	61	54	69
SA Surveys with Condition-Level Deficiencies	25	30	22	31
AO Surveys with Missed Comparable Deficiencies	21	24	17	29
Disparity Rate	32%	39%	31%	42%
Sampling Fraction	.11	.10	.09	.09

\*Psychiatric hospitals were not part of the validation program as a separate program type until FY 2012. The psychiatric hospital accreditation program received initial CMS-approval in FY 2011.

The Hospice and HHA disparity rates are significantly different than the other facility types due to the lower percentage of surveys with condition-level deficiencies cited by SAs in the 60-day validation samples for both hospice and HHAs for FYs 2012–2015. This lower deficiency rate is primarily due to these facility types not having deficiencies related to PE conditions. There is no PE condition for HHAs since these services are provided in the patient’s home. Although hospices do have a PE condition, a number of hospice services are provided in the patient’s home as well.

In FY 2015, the disparity rates for psychiatric hospitals and CAHs decreased by six percent and seven percent respectively from FY 2014. The remaining program types’ disparity rates increased from FYs 2014 to 2015 with hospitals having only a one percent increase. ASCs had the largest increase in the disparity rate of all the program types from FYs 2014 to 2015, with an 11 percent increase.

### **Validation Performance Results: Individual Accrediting Organizations**

Each AO receives feedback on the results of CMS’ analysis of 60-day validation surveys for its deemed status facilities. The series of tables below, presents the results of the 60-day validation surveys by facility type for each of the AO Medicare accreditation programs from FYs 2012–2015. (See Tables 10-15.)

When the number of 60-day validation surveys completed by the SA is less than five surveys, the disparity rate is not presented. The small 60-day validation sample sizes limited the analysis of some AO programs. Since 2008, CMS has tried to significantly increase the number of 60-day validation samples. With minimal exception, the sample size for every AO program was either maintained or increased from FYs 2011 to 2012. Due to decreased funding in FY 2013, the sample size decreased for each program type, with the exception of psychiatric hospitals and CAHs. In FY 2014, the number of validation surveys for CAHs, HHAs, Hospices and ASCs decreased, also as a result of decreased funding. In FY 2015, the number of validation surveys for these same program types increased. Only hospitals showed a decrease in the number of surveys performed from FY 2014 to FY 2015. CMS strives to maintain a larger sample size in

the future based on the availability of Federal funds. The presentation of validation results over several time periods provides a more complete examination of the consistency of individual AO performance. Therefore, the results for the FYs 2012–2014 60-day validation surveys for individual AOs have been combined in the tables below to provide a more robust and reliable estimate of the disparity rates.

## Hospital

The AOs with hospital programs in FY 2015 were AOA/HFAP, CIHQ, DNV GL, and TJC. (See Table 10 and Graphs 6-7.)

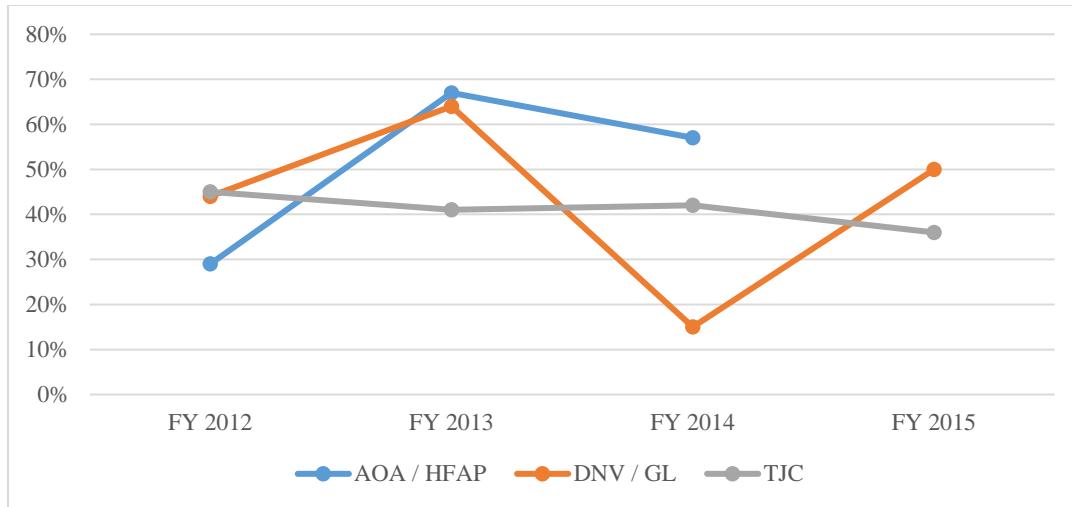
**Table 10**  
**Hospital 60-Day Validation Survey Results by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**

	AOA/HFAP				DNV/GL				TJC				Total FYs 2012- 2015
	FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015	
60-Day Validation Sample Surveys	7	9	7	4	9	11	20	8	86	76	76	89	402
SA Surveys with Condition-Level Deficiencies	2	6	4	*N/A	4	9	3	5	44	37	34	33	181
AO Surveys with Missed Comparable Deficiencies	2	6	4	*N/A	4	7	3	4	39	31	32	32	164
Disparity Rate	29%	67%	57%	*N/A	44%	64%	15%	50%	45%	41%	42%	36%	41%
Sampling Fraction	.02	.16	.11	*N/A	.09	.11	.20	.07	.07	.06	.07	.08	.07

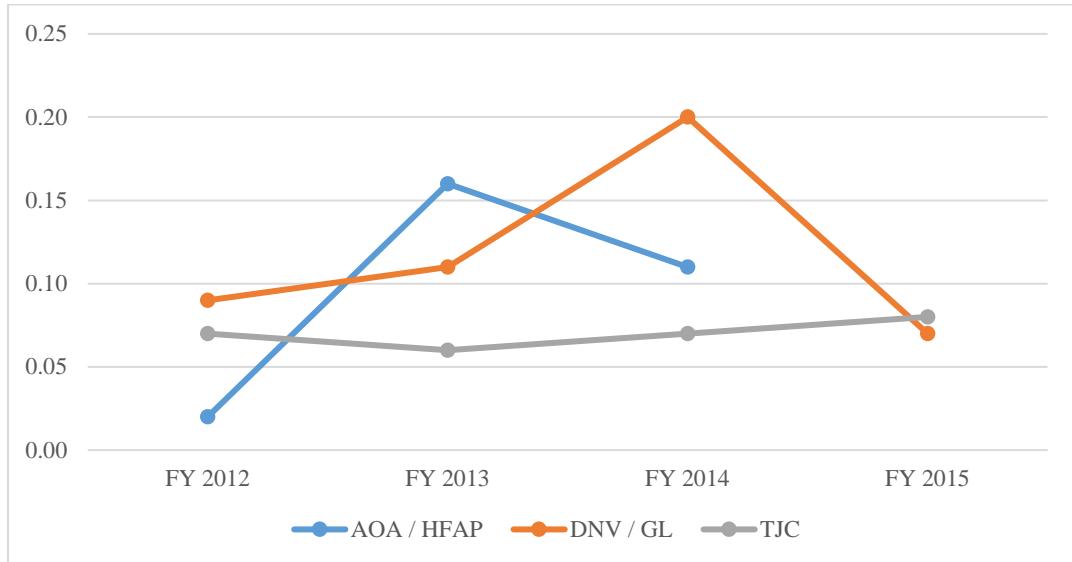
\*N/A: When a minimum sample size of five is not achieved for an AO, no data is reported given the lack of statistical significance.

Note: CIHQ hospital accreditation program received initial CMS approval July 2013. No CIHQ selections in FY 2014. CIHQ 2015 had one validation survey completed, resulting in no data for comparison.

**Graph 6**  
**Hospital 60-Day Validation Survey Disparity Rate Results**  
**by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**



**Graph 7**  
**Hospital 60-Day Validation Survey Sampling Fraction Results**  
**by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**



- **AOA/HFAP:** In FY 2015, due to the low number of deemed hospitals due for resurvey, only four validation surveys were conducted. Therefore, no additional data is reported.
- **CIHQ:** As a result of being a newly accredited AO, CIHQ completed only one validation survey in FY 2015. Therefore, no additional data is reported.

- **DNV GL:** In FY 2015, the disparity rate was 50 percent based on the completion of eight validation surveys. The number of validation surveys conducted represents a seven percent sample of the surveys conducted by DNV GL. The FY 2015 disparity rate is higher than the FY 2012 disparity rate of 44 percent which was based on a 9 percent sample of the surveys conducted during that period.
- **TJC:** In FY 2015, the disparity rate was 36 percent based on the completion of 89 validation surveys. The number of validation surveys conducted represents an eight percent sample of surveys conducted by TJC. The FY 2015 disparity rate is nine percentage points lower than the disparity rate for FY 2012 which was based on a seven percent sample of surveys conducted during that period.

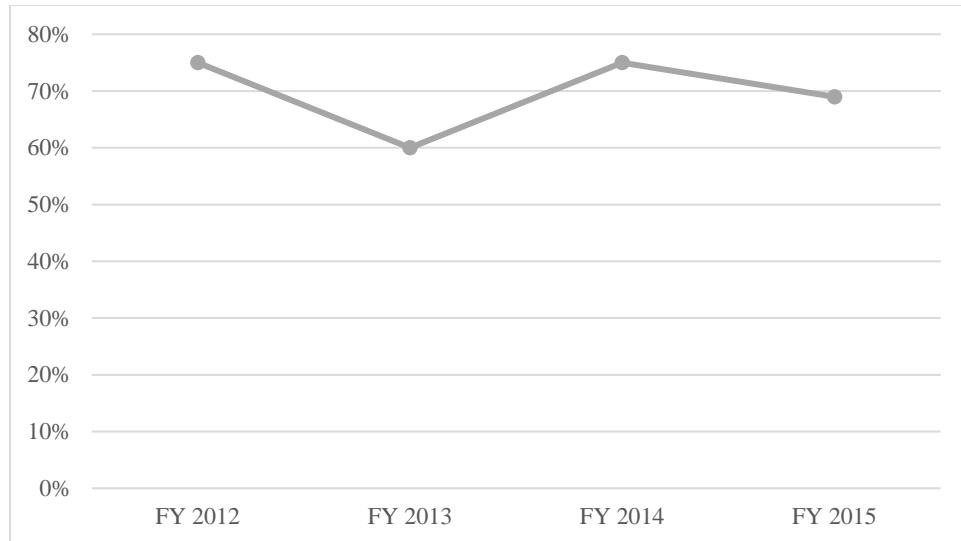
### **Psychiatric Hospital**

TJC was the only AO with a CMS-approved psychiatric hospital Medicare accreditation program in FY 2015. The psychiatric hospital program was initially approved by CMS in FY 2011. (See Table 11 and Graphs 8-9.)

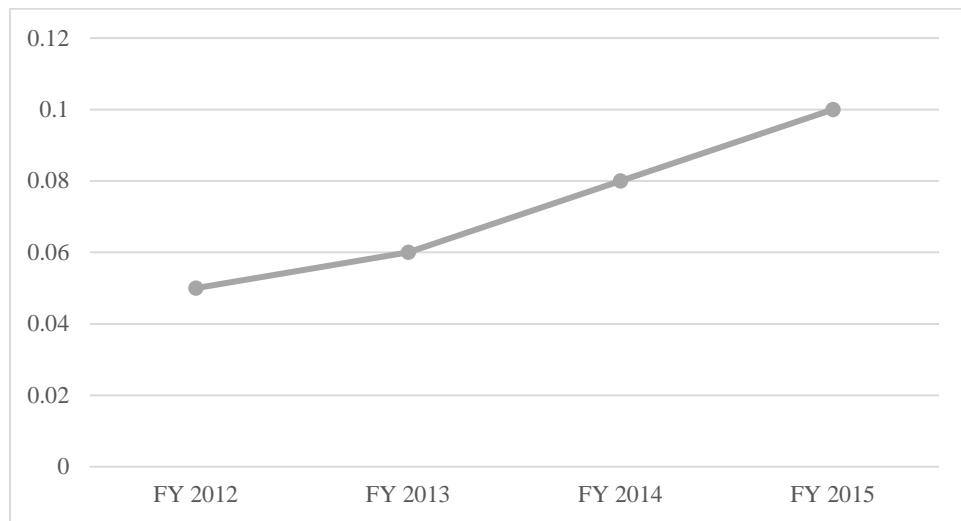
**Table 11**  
**Psychiatric Hospital 60-Day Validation Survey Results by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**

	TJC				Total FYs 2012– 2015
	FY 2012	FY 2013	FY 2014	FY 2015	
60-Day Validation Sample Surveys	8	10	12	16	46
SA Surveys with Condition-Level Deficiencies	6	6	10	12	34
AO Surveys with Missed Comparable Deficiencies	6	6	9	11	32
Disparity Rate	75%	60%	75%	69%	70%
Sampling Fraction	.05	.06	.08	.10	.07

**Graph 8**  
**Psychiatric Hospital 60-Day Validation Survey Disparity Rate Results  
by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**



**Graph 9**  
**Psychiatric Hospital 60-Day Validation Survey Sampling Fraction Results  
by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**



- TJC:** In FY 2015, the disparity rate was 69 percent based on the completion of 16 validation surveys. The number of validation surveys completed represents a 10 percent sample of the surveys conducted by the TJC. The FY 2015 disparity rate is six percentage points lower than the disparity rate of 75 percent for FY 2012 which was based on a five percent sample of the surveys conducted during that period. Of the overall disparity rate of 69 percent for FY 2015, the health and safety disparity rate was 62.5 percent, and the PE disparity rate was 37.5 percent. This continues to be the trend from FYs 2012 to 2014. This raised serious concerns about TJC's ability to appropriately identify and cite health and safety deficient practices in addition to PE deficiencies during the survey process. In addition, this is the first time that the health and safety disparity rate has been the primary driver for the overall disparity rate for an accreditation program. As a result of this high disparity rate and the serious nature of other corporate on-site findings, CMS opened a 180-day performance review in December 2015 in accordance with 42 CFR § 488.8(c). Satisfactory progress was not demonstrated during the 180 day performance review period resulting in TJC being moved to a probationary status for 180 days in order to provide TJC with additional time to fully implement and sustain the required corrections to remain as an AO with the Medicare program. TJC had made significant progress in the areas of health and safety concerns during the probationary status period, resulting in their being removed from probationary status.

## Critical Access Hospital

The AOs with CAH accreditation programs in FY 2015 were AOA/HFAP, DNV GL, and TJC. (See Table 12 and Graphs 10-11.)

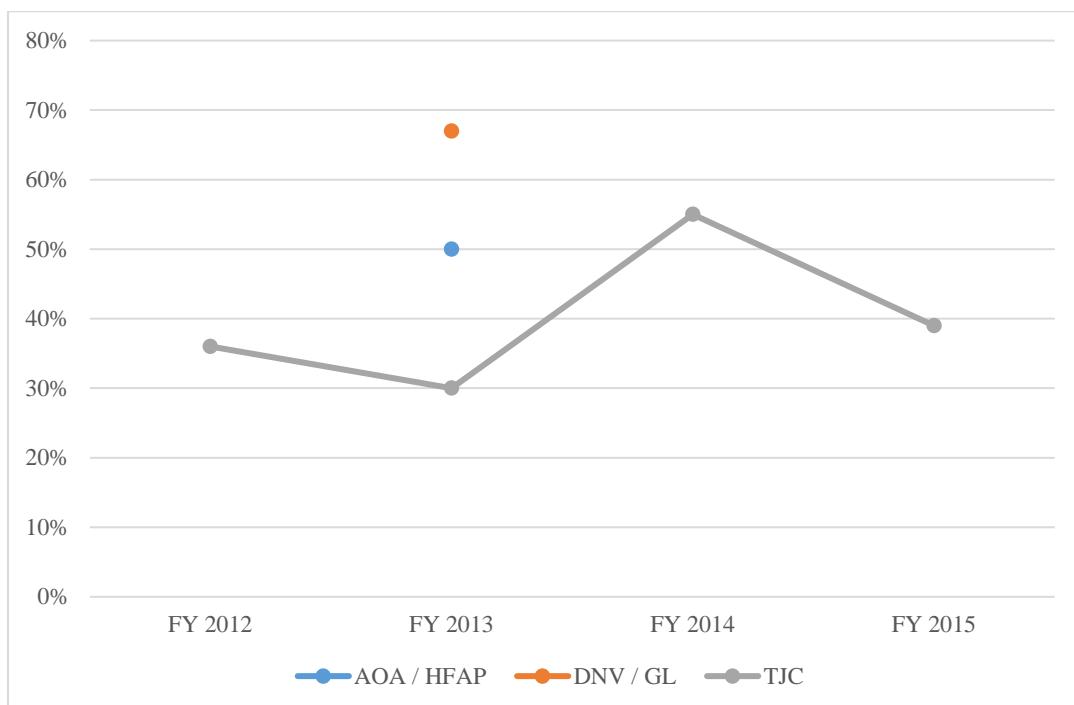
**Table 12**  
**Critical Access Hospital 60-Day Validation Survey Results**  
**by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**

	AOA/HFAP				DNV GL				TJC				Total FYs 2012– 2015
	FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015	
60-Day Validation Sample Surveys	2	6	1	3	3	6	4	2	28	23	22	28	128
SA Surveys with Condition-Level Deficiencies	*N/A	4	*N/A	*N/A	*N/A	4	*N/A	*N/A	13	9	13	11	54
AO Surveys with Missed Comparable Deficiencies	*N/A	3	*N/A	*N/A	*N/A	4	*N/A	*N/A	10	7	12	11	47

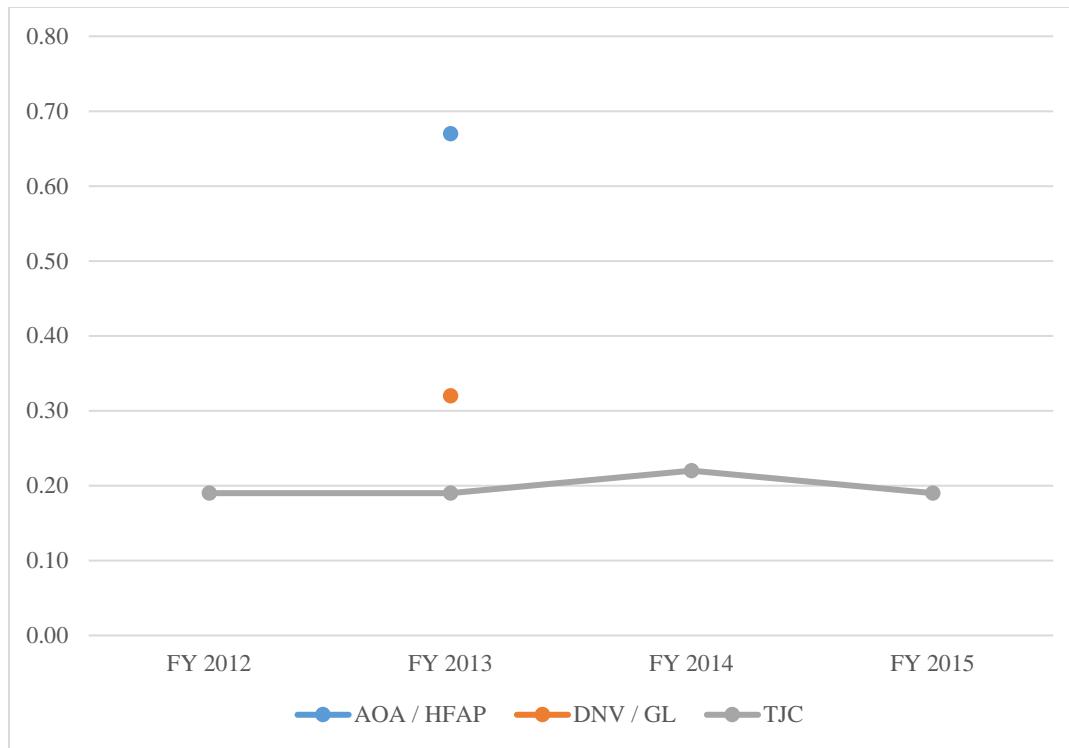
	AOA/HFAP					DNV GL				TJC				Total FYs 2012– 2015
	FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015	Total FYs 2012– 2015	
Disparity Rate	*N/A	50%	*N/A	*N/A	*N/A	67%	*N/A	*N/A	36%	30%	55%	39%	37%	
Sampling Fraction	*N/A	.67	*N/A	*N/A	*N/A	.32	*N/A	*N/A	.19	.19	.22	.19	.17	

\*N/A: When a minimum sample size of five is not achieved for an AO, no data is reported given the lack of statistical significance.

**Graph 10**  
**Critical Access Hospital 60-Day Validation Survey Disparity Rate Results**  
**by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**



**Graph 11**  
**Critical Access Hospital 60-Day Validation Survey Sampling Fraction Results**  
**by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**



- **AOA/HFAP:** In FY 2015, due to the low number of deemed CAHs due for resurvey, only three validation surveys were conducted. Therefore, no additional data is reported.
- **DNV GL:** In FY 2015, due to the low number of deemed CAHs due for resurvey, only two validation surveys were conducted. Therefore, no additional data is reported.
- **TJC:** In FY 2015, the disparity rate was 39 percent based on the completion of 28 validation surveys. The number of validation surveys completed represents a 19 percent sample of the surveys conducted by TJC. The FY 2015 disparity rate is slightly higher than the FY 2012 disparity rate of 36 percent which was also based on a 19 percent sample of surveys conducted during that period.

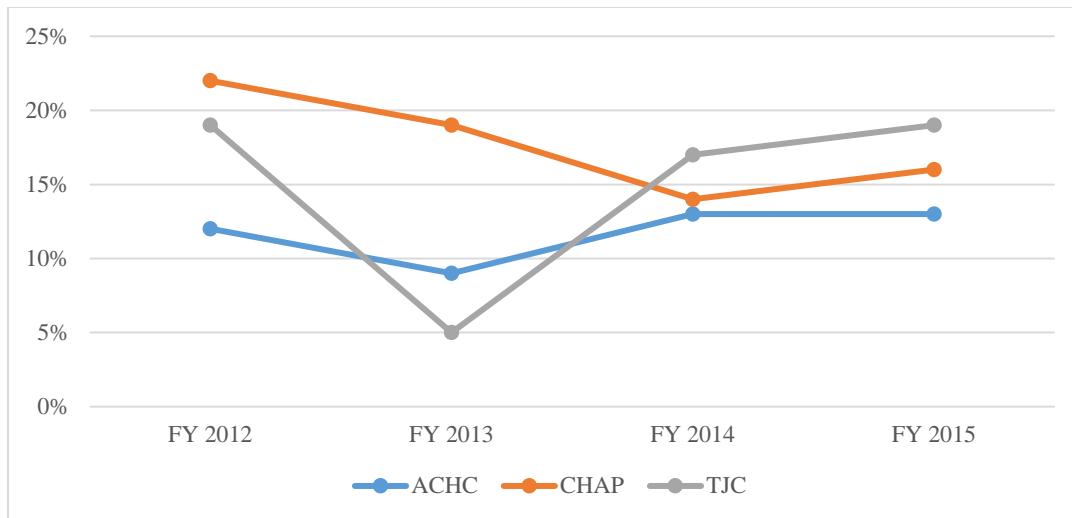
## **Home Health Agency**

The AOs with HHA accreditation programs in FY 2015 were ACHC, CHAP, and TJC. (See Table 13 and Graphs 12–13.)

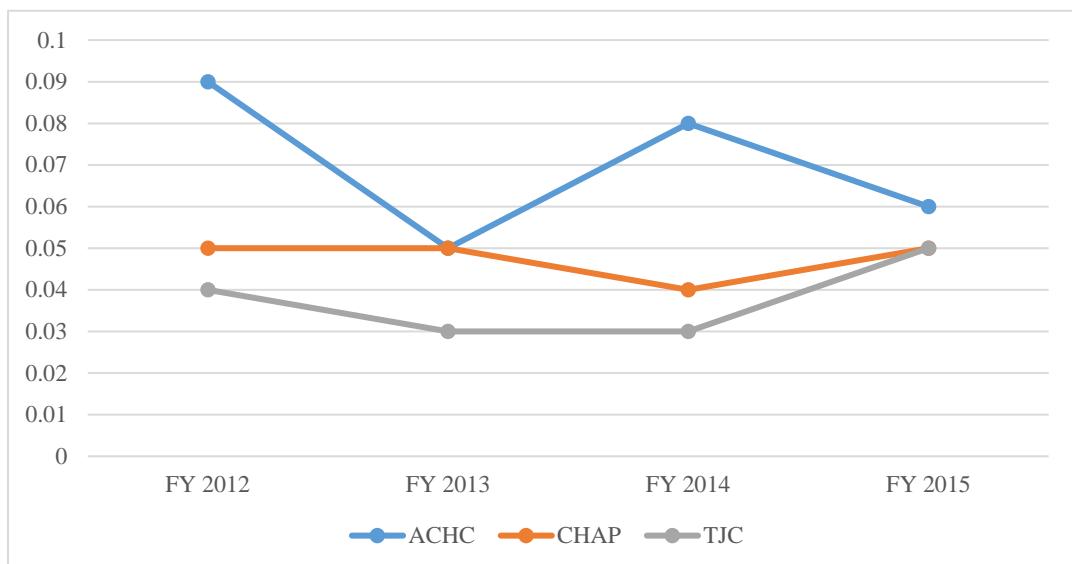
**Table 13**  
**Home Health Agency 60-Day Validation Survey Results**  
**by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**

	ACHC				CHAP				TJC				Total
	FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015	
60-Day Validation Sample Surveys	25	11	23	16	50	48	28	51	27	21	24	37	361
SA Surveys with Condition-Level Deficiencies	6	3	3	3	17	11	4	8	7	1	9	12	84
AO Surveys with Missed Comparable Deficiencies	3	1	3	2	11	9	4	8	5	1	4	7	58
Disparity Rate	12%	9%	13%	13%	22%	19%	14%	16%	19%	5%	17%	19%	16%
Sampling Fraction	.09	.05	.08	.06	.05	.05	.04	.05	.04	.03	.03	.05	.05

**Graph 12**  
**Home Health Agency 60-Day Validation Survey Disparity Rate Results**  
**by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**



**Graph 13**  
**Home Health Agency 60-Day Validation Survey Sampling Fraction Results**  
**by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**



- **ACHC:** In FY 2015, the disparity rate was 13 percent based on the completion of 16 validation surveys. The number of validation surveys completed represents a six percent sample of surveys conducted by ACHC. The FY 2015 disparity rate slightly increased from FY 2012 disparity rate of 12 percent which was based on a 9 percent sample of surveys conducted during that period.
- **CHAP:** In FY 2015, the disparity rate was 16 percent based on the completion of 51 validation surveys. The number of validation surveys completed represents a five percent sample of the surveys conducted by CHAP. This is lower than the FY 2012 disparity rate of 22 percent which was also based on a 5 percent sample of the surveys conducted during that time.
- **TJC:** In FY 2015, the disparity rate was 19 percent based on the completion of 37 validation surveys. The number of validation surveys completed represents a five percent sample of the surveys conducted by TJC. The FY 2012 disparity rate was also 19 percent based on a 4 percent sample of the surveys conducted during that period.

## Hospice

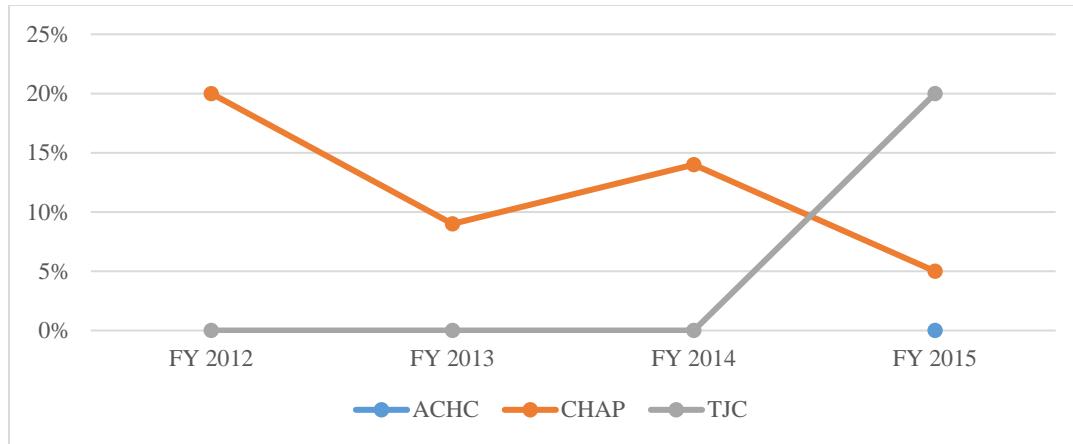
The AOs with hospice accreditation programs in FY 2015 were ACHC, CHAP and TJC. (See Table 14 and Graphs 14-15.)

**Table 14**  
**Hospice 60-Day Validation Survey Results**  
**by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**

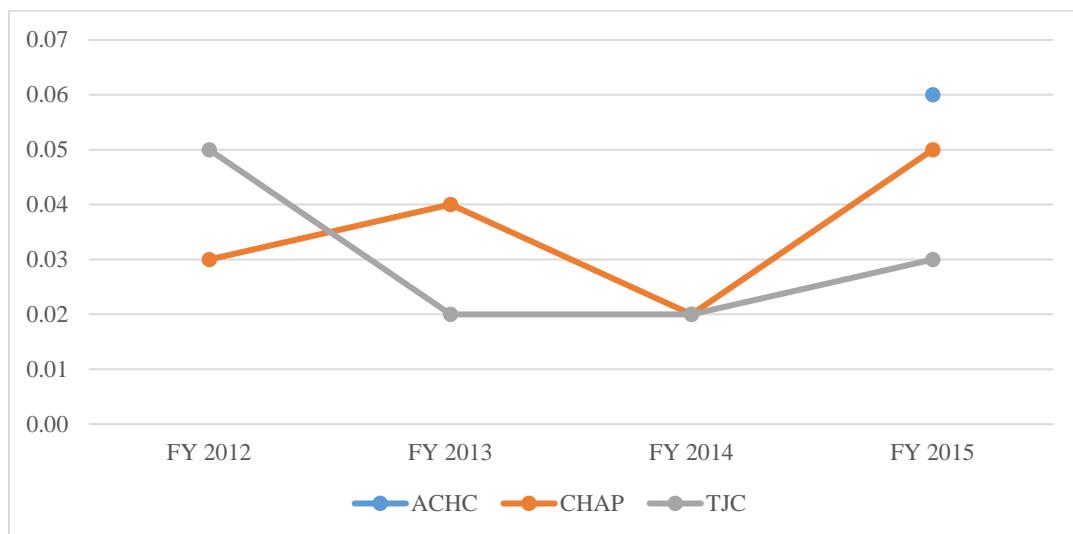
	ACHC				CHAP				TJC				Total
	FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015	
60-Day Validation Sample Surveys	1	1	1	5	10	11	7	19	10	6	8	10	89
SA Surveys with Condition-Level Deficiencies	*N/A	*N/A	*N/A	0	2	1	1	2	0	0	1	2	9
AO Surveys with Missed Comparable Deficiencies	*N/A	*N/A	*N/A	0	2	1	1	1	0	0	0	2	7
Disparity Rate	*N/A	*N/A	*N/A	0%	20%	9%	14%	5%	0%	0%	0%	20%	8%
Sampling Fraction	*N/A	*N/A	*N/A	.06	.03	.04	.02	.05	.05	.02	.02	.03	.03

\*N/A: When a minimum sample size of five is not achieved for an AO, no data is reported given the lack of statistical significance.

**Graph 14**  
**Hospice 60-Day Validation Survey Disparity Rate Results**  
**by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**



**Graph 15**  
**Hospice 60-Day Validation Survey Sampling Fraction Results**  
**by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**



- **ACHC:** In FY 2015, CMS selected five ACHC hospice validation surveys for which no CoPs were identified. Due to the low number of deemed hospices due for resurvey in FY 2012, CMS selected only one ACHC hospice validation survey for which no CoPs were identified.
- **CHAP:** In FY 2015, the disparity rate was 5 percent based on the completion of 19 validation surveys. The number of validation surveys completed represents a five percent sample of the surveys performed by CHAP. The FY 2015 disparity rate is significantly

lower than the disparity rate of 20 percent in FY 2012 based on a 3 percent sample of the surveys conducted during that period. In FY 2015, the sample size was larger than the sample sizes in FYs 2012–2014 and the number of CoPs identified by the SA was small. At the same time, the number of CoPs missed by CHAP was also small. These factors contributed to the large decrease in the disparity rate from FY 2012 to FY 2015.

- **TJC:** In FY 2015, the disparity rate was 20 percent based on the completion of 10 validation surveys. The number of validation surveys completed represents a three percent sample of the surveys performed by TJC. In FY 2012 and FY 2013, no condition-level deficiencies were cited by the SA. In FY 2014, no condition-level deficiencies were missed by the AO. In FY 2015, each of the condition-levels cited by the SA were missed by the AO which contributed to the large increase in the disparity rate.

### **Ambulatory Surgery Center**

The AOs with ASC accreditation programs in FY 2015 were AAAASF, AAAHC, AOA/HFAP, and TJC. (See Table 15 and Graphs 16-17.)

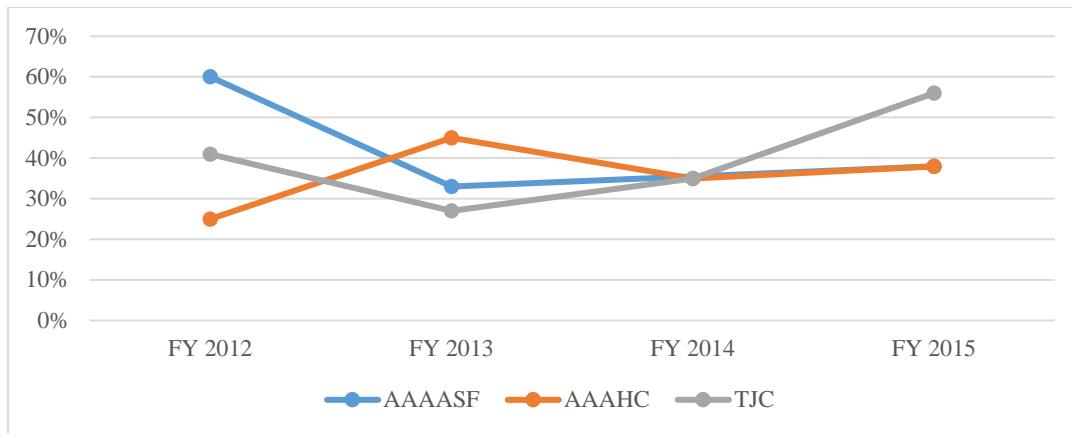
**Table 15**  
**Ambulatory Surgery Center 60-Day Validation Survey Results**  
**by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**

	AAAASF				AAAHC				AOA/HFAP**			TJC				Total
	FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015	
60-Day Validation Sample Surveys	5	6	4	8	44	38	26	42	2	1	1	17	15	23	18	250
SA Surveys with Condition-Level Deficiencies	3	3	*N/A	3	14	21	13	17	*N/A	*N/A	*N/A	8	5	9	10	106
AO Surveys with Missed Comparable Deficiencies	3	2	*N/A	3	11	17	9	16	*N/A	*N/A	*N/A	7	4	8	10	90
Disparity Rate	60%	33%	*N/A	38%	25%	45%	35%	38%	*N/A	*N/A	*N/A	41%	27%	35%	56%	36%
Sampling Fraction	.05	.07	*N/A	.09	.12	.12	.09	.11	*N/A	*N/A	*N/A	.11	.08	.10	.08	.10

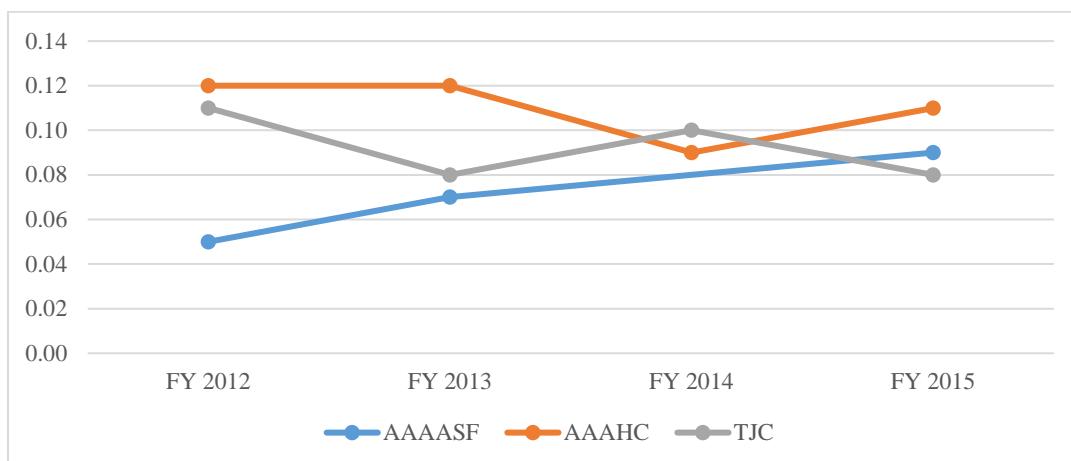
\*N/A: When a minimum sample size of five is not achieved for an AO, no data is reported given the lack of statistical significance.

\*\*Very few AOA/HFAP ASC validation survey selections have been made since FY 2012 due to the low numbers of deemed ASCs.

**Graph 16**  
**Ambulatory Surgery Center 60-Day Validation Survey Disparity Rate Results  
by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**



**Graph 17**  
**Ambulatory Surgery Center 60-Day Validation Survey Sampling Fraction Results  
by Accrediting Organization (AO)**  
**Fiscal Years (FYs) 2012–2015**



- **AAAASF:** In FY 2015, the disparity rate was 38 percent based on the completion of eight validation surveys. The number of validation surveys completed represents a nine percent sample of the surveys performed by AAAASF. The FY 2015 disparity rate is lower than the disparity rate of 60 percent in FY 2012 based on a 5 percent sample of the surveys conducted during that period. The larger sample size in FY 2015 contributed to the decrease in disparity rate.
- **AAAHC:** In FY 2015, the disparity rate was 38 percent based on the completion of 42 validation surveys. The number of validation surveys completed represents an 11 percent sample of the surveys performed by AAAHC. The FY 2015 disparity rate is 13 percentage

points higher than the disparity rate of 25 percent in FY 2012 which was based on a 12 percent sample of the surveys conducted during that period. The FY 2015 sample size is slightly smaller than the FY 2012 sample size. Additionally, both the number of condition-level deficiencies identified by the SA and the number of those condition-level deficiencies missed by the AO increased from FY 2012 to FY 2015. These factors contributed to the increase in the disparity rate.

- **AOA/HFAP:** Due to the consistently low number of deemed AOA/HFAP ASCs, only one validation survey was conducted in FY 2015. Therefore, no additional data is reported.
- **TJC:** In FY 2015, the disparity rate was 56 percent based on the completion of 18 validation surveys. The number of validation surveys completed represents an eight percent sample of the surveys performed by TJC. The FY 2015 disparity rate is 15 percentage points higher than FY 2012 disparity rate of 41 percent which was based on an 11 percent sample of the surveys conducted during that period. In FY 2015, the sample size was slightly larger than the sample size in FY 2012. Additionally, the number of condition-level deficiencies cited by the SA and missed by the AO increased from FY 2012 to FY 2015. These factors contributed to the large increase in the disparity rate.

### **Validation Performance Results: Physical Environment vs. Other Health Conditions Cited**

Examining the specific condition-level deficiencies cited by the SAs across all 60-day validation surveys provides an indication of the types of quality problems that exist in these facility types as well as the relationship between SA and AO citations for specific conditions. CMS uses two approaches for this analysis: (1) a review of the types of condition-level citations identified by SAs and the comparable AO deficiency findings; and (2) a comparison of the number of surveys with PE condition-level deficiencies and the number of surveys with other types of condition-level deficiencies. Both approaches highlight the same conclusion: SAs identify more PE condition-level deficiencies than any other type of deficiency on validation surveys; and AOs miss a significant number of these PE deficiencies. These findings are consistent with validation analysis results for the past several years with two exceptions. In FYs 2014–2015, the SAs identified more health and safety condition-level deficiencies than PE condition-level deficiencies in psychiatric hospitals. In FY 2015, the same is true for ASCs.

### **Comparison of State Agency and Accrediting Organization Condition-Level Citation Findings**

The first analysis yields the number of facilities cited by SAs for specific condition-level deficiencies and the number of surveys where the AOs missed citing comparable deficiencies. These results are discussed below by each specific facility type. (See Tables 16-21.)

**Table 16**  
**Number and Type of Condition-Level Deficiencies**  
**Cited on 60-Day Validation Surveys**  
**Hospitals**  
**Fiscal Year 2015**

Medicare Conditions*	Cited by SA	Missed by AO
Sample Size – 102		
Governing Body	8	6
Patient Rights	7	4
Quality Assurance Performance Improvement (QAPI)	3	3
Nursing Services	2	1
Medical Record Services	2	2
Pharmaceutical Services	1	0
Food and Dietetic Services	3	3
<b>Physical Environment*</b>	<b>27</b>	<b>27</b>
Infection Control	10	7
Discharge Planning	1	1
Organ, Tissue, and Eye Procurement	2	1
Respiratory Care Services	1	1
<b>TOTAL</b>	<b>67</b>	<b>56</b>

\*Most frequently cited deficiency.

Note: PE refers to the number of PE CoPs, which includes the National Fire Protection Association (NFPA) LSC requirements CMS has adopted as part of its health and safety standards.

In FY 2015, the hospital sample consisted of 102 validation surveys. In this sample, 42 facilities were cited at the condition-level by the SAs. **PE** was the most prevalent condition-level deficiency cited by the SAs with 27 condition-level citations. The AOs missed the same number of comparable deficiencies for PE. The findings regarding PE were similar in FYs 2012–2014.

In FY 2015, the next most frequently SA-cited conditions were: Infection Control, cited 10 times by the SAs and missed 7 times by the AOs, and Governing Body, cited 8 times by the SAs and missed 6 times by the AOs.

**Table 17**  
**Number and Type of Condition-Level Deficiencies**  
**Cited on 60-Day Validation Surveys**  
**Psychiatric Hospitals**  
**Fiscal Year 2015**

Medicare Conditions Sample Size – 16	Cited by SA	Missed by AO
Governing Body	2	2
Patient Rights	4	2
QAPI	5	4
Medical Staff	1	1
Pharmaceutical Services	1	1
Radiologic Services	2	1
Food and Dietetic Services	2	2
PE	6	6
Infection Control	3	2
Organ, Tissue, and Eye Procurement	1	1
Rehabilitation Services	1	1
Respiratory Care Services	1	1
Special Provisions Applying to Psychiatric Hospitals	2	1
<b>Special Medical Record Requirements for Psychiatric Hospitals*</b>	<b>14</b>	<b>9</b>
Special Staff Requirements for Psychiatric Hospitals	3	3
<b>TOTAL</b>	<b>48</b>	<b>37</b>

\*Most frequently cited deficiency

In FY 2015, the psychiatric hospital sample consisted of 16 validation surveys. In this sample, 12 facilities were cited at the condition-level by the SAs. **Special Medical Record Requirements for Psychiatric Hospitals** was the most prevalent condition-level deficiency cited by the SAs with 14 SA condition-level citations. The AO missed nine comparable deficiencies.

In FY 2015, the next most frequently SA-cited condition for psychiatric hospitals was PE, with six SA condition-level citations. The same number of comparable deficiencies were missed by the AO. In FY 2014, Special Medical Record Requirements for psychiatric hospitals was also the most frequently cited condition-level deficiency by the SAs with seven SA condition-level citations. The AO missed four comparable deficiencies.

**Table 18**  
**Number and Type of Condition-Level Deficiencies**  
**Cited on 60-Day Validation Surveys**  
**Critical Access Hospitals**  
**Fiscal Year 2015**

Medicare Conditions Sample Size – 33	Cited by SA	Missed by AO
Compliance with Federal, State, Local Laws, & Regulation	1	1
Emergency Services	2	2
<b>Physical Plant and Environment*</b>	<b>10</b>	<b>8</b>
Organizational Structure	2	2
Provision of Services	7	5
Clinical Records	2	1
Surgical Services	5	3
Periodic Evaluation and Quality Assurance (QA) Review	2	1
Special Requirements for CAH Providers of LTC Services	2	2
<b>TOTAL</b>	<b>33</b>	<b>25</b>

\*Most frequently cited deficiency

In FY 2015, the CAH sample consisted of 33 validation surveys. In this sample, 15 facilities were cited at the condition-level by the SAs. **Physical Plant and Environment** was the most prevalent condition-level deficiency cited by the SAs with 10 SA condition-level citations. The AOs missed eight comparable deficiencies for PE, which was also the most frequently cited condition in FYs 2012–2014.

In FY 2015, the next most frequently SA-cited condition for CAHs was Provision of Services with seven SA condition-level citations and five comparable deficiencies missed by the AOs.

**Table 19**  
**Number and Type of Condition-Level Deficiencies**  
**Cited on 60-Day Validation Surveys**  
**Home Health Agencies**  
**Fiscal Year 2015**

Medicare Conditions Sample Size – 104	Cited by SA	Missed by AO
Release of Patient Identifiable Oasis Information	1	1
Organization, Services, and Administration	9	6
Group of Professional Personnel	3	2
<b>Acceptance of Patients, Plan of Care &amp; Medical Supervision*</b>	<b>15</b>	<b>8</b>
Reporting Oasis Information	2	1
Skilled Nursing Services	8	4
Therapy Services	1	1
Home Health Aide Services	9	5
Clinical Records	5	4
Evaluation of the Agency's Program	9	4
Comprehensive Assessment of Patients	10	4
<b>TOTAL</b>	<b>72</b>	<b>40</b>

\*Most frequently cited deficiency

In FY 2015, the HHA sample consisted of 104 validation surveys. In this sample, 23 facilities were cited for condition-level deficiencies by the SAs. The most frequently cited condition was **Acceptance of Patients, Plan of Care & Medical Supervision**, with 15 SA condition-level citations and 8 comparable deficiencies missed by the AOs.

In FY 2015, the next most frequently cited condition was Comprehensive Assessment of Patients with 10 SA condition-level citations and 4 comparable deficiencies missed by the AO.

**Table 20**  
**Number and Type of Condition-Level Deficiencies**  
**Cited on 60-Day Validation Surveys**  
**Hospices**  
**Fiscal Year 2015**

Medicare Conditions Sample Size – 34	Cited by SA	Missed by AO
Hospices that Provide Inpatient Care Directly	1	1
Residents of SNF/NF or ICF/MR	1	1
Initial & Comprehensive Assessment of Patient	1	1

Medicare Conditions Sample Size – 34	Cited by SA	Missed by AO
<b>Interdisciplinary Group (IDG), Care Planning, Coordination of Services*</b>	<b>2</b>	<b>1</b>
<b>TOTAL</b>	<b>5</b>	<b>4</b>

\*Most frequently cited deficiency

In FY 2015, the Hospice sample consisted of 34 validation surveys. In this sample, four facilities were cited for condition-level deficiencies by the SAs. The most frequently cited condition was **IDG, Care Planning, Coordination of Services**, with two SA condition-level citations and one comparable deficiency missed by the AOs.

**Table 21**  
**Number and Type of Condition-Level Deficiencies**  
**Cited on 60-Day Validation Surveys**  
**Ambulatory Surgery Centers**  
**Fiscal Year 2015**

Medicare Conditions Sample Size – 69	Cited by SA	Missed by AO
Basic Requirements	1	1
Governing Body and Management	21	15
Surgical Services	2	1
Quality Assessment & Performance Improvement	8	4
Physical Environment	13	12
Medical Staff	7	4
Nursing Services	4	3
Medical Records	1	1
Pharmaceutical Services	7	6
Laboratory and Radiologic Services	4	4
Patient Rights	2	2
<b>Infection Control*</b>	<b>23</b>	<b>15</b>
Patient Admission, Assessment and Discharge	4	3
<b>TOTAL</b>	<b>97</b>	<b>71</b>

\*Most frequently cited deficiency

In FY 2015, the ASC sample consisted of 69 validation surveys. In this sample, 31 facilities were cited for condition-level deficiencies by the SAs. The most frequently cited condition was **Infection Control**, with 23 SA condition-level citations. The AOs missed 15 comparable deficiencies for Infection Control. The next most frequently cited condition was PE, which was cited 13 times by the SAs and missed 12 times by the AOs. In FY 2014, PE was the most

frequently cited condition followed by Infection Control.

#### Comparison of Deficiencies for Physical Environment and Other Health Conditions

The second analysis compares the validation results for condition-level deficiencies for PE conditions with the results for condition-level deficiencies for all other conditions and yields two disparity rates for each type of facility and AO. (See Tables 22-23 and Graph 18.)

**Table 22**  
**Number of 60-Day Validation Surveys for**  
**Facility Types with Life Safety Code Requirements**  
**(Fiscal Year 2015)**

Validation Survey Analysis	Hospital*	Psych Hospital	CAH	ASC
60-Day Validation Sample Surveys	102	16	33	69

\*Acute Care and LTCHs

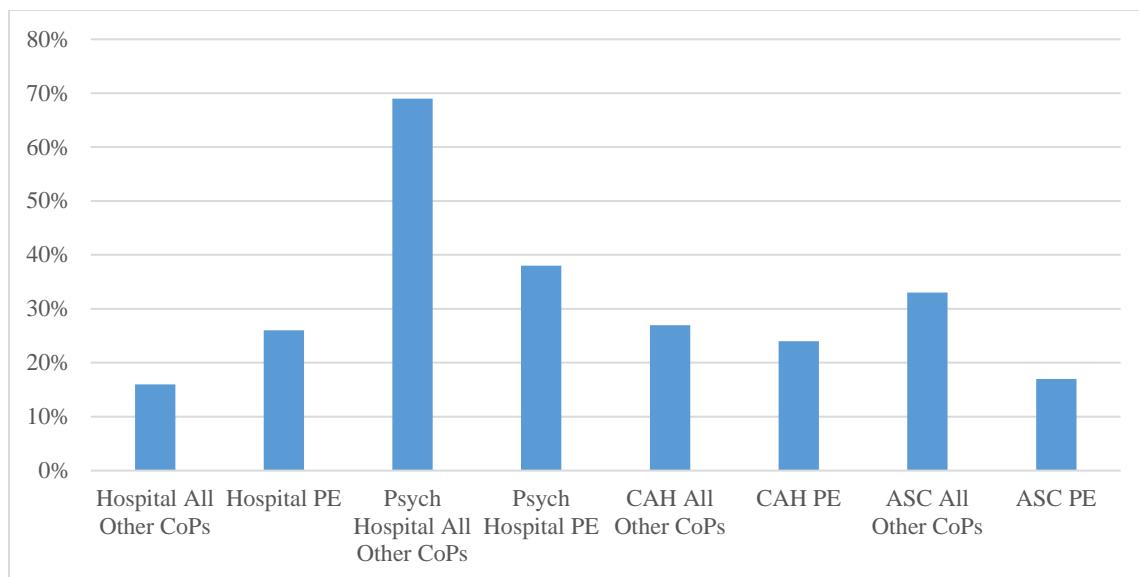
**Table 23**  
**60-Day Validation Survey Results**  
**Comparison between All Other Conditions of Participation (CoPs) Cited and**  
**Physical Environment (PE) for Facility Types with Life Safety Code Requirements**  
**Fiscal Year 2015**

	Hospital All Other CoPs	Hospital PE	Psych Hospital All Other CoPs	Psych Hospital PE	CAH All Other CoPs	CAH PE	ASC All Other CoPs	ASC PE
SA Surveys with Condition-Level Deficiencies	25	27	18	6	13	10	34	13
AO Surveys with Missed Comparable Deficiencies	16	27	11	6	9	8	23	12
Disparity Rate	16%	26%	69%	38%	27%	24%	33%	17%

In FY 2015, PE continued to have a significant impact on the overall disparity rate for each facility type. The FY 2015 results show that the PE condition is still the single largest driver of the disparity rate for hospitals. For hospitals, the disparity rate based on the PE condition is 10 percentage points higher than the disparity rate calculated based on other health and safety conditions. However, this range is slightly lower compared to the hospital PE disparity rate that was 13 percentage points higher than other health and safety conditions in FY 2014. The PE disparity rate for ASCs was 16 percentage points lower than the disparity rate for other health

and safety conditions in FY 2015 compared to 5 percentage points higher in FY 2014. In FY 2015, the PE disparity rate for psychiatric hospitals was 31 percentage points lower than the disparity rate for other health and safety conditions. In FY 2014, the PE disparity rate for psychiatric hospitals was only 17 percentage points lower than the disparity rate for other health and safety conditions. In FY 2015, the PE disparity rate for CAHs was three percentage points lower than the disparity rate for other health and safety conditions. This is a significant improvement from FY 2014 when the PE disparity rate was 22 percentage points higher than the disparity rate for other health and safety conditions. (See Graph 18.)

**Graph 18**  
**60-Day Validation Survey Disparity Rate Results**  
**Comparison between All Other Conditions of Participation (CoPs) Cited and**  
**Physical Environment (PE) for Facility Types with Life Safety Code Requirements**  
**Fiscal Year 2015**

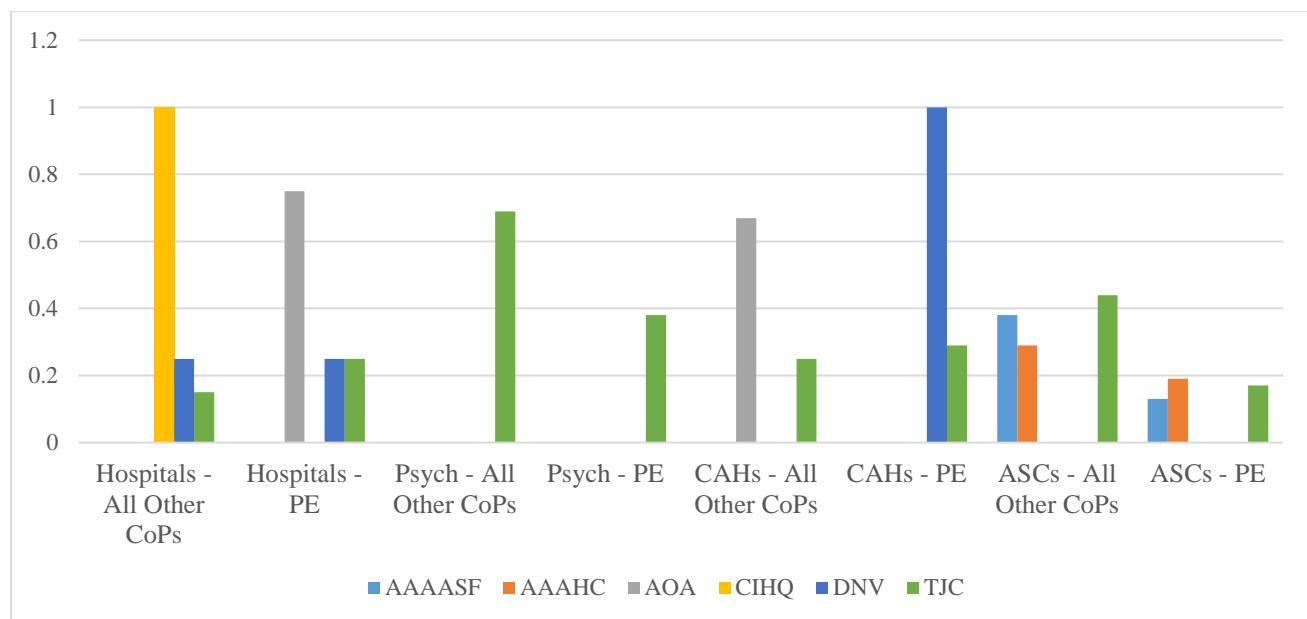


The majority of the PE disparity rates consists of LSC deficiencies. CMS generates a report which identifies the top disparate LSC deficiencies as determined by the validation analysis. This report is provided annually to the AOs. These top LSC disparate deficiencies are consistent with deficiencies cited in FYs 2009 through 2014. This report is shared with the AOs and is intended to provide the AOs with an understanding of the emphasis of CMS LSC surveys which will allow the AOs to ensure their programs are surveying the same LSC provisions. An emphasis on the top disparate LSC deficiencies should assist the AOs in their efforts to reduce LSC disparities.

The AOs have had difficulty identifying deficiencies that SAs have cited related to the requirements in the 2000 edition of the LSC, which CMS adopted by regulation. CMS has been working with all AOs to provide guidance on the source of this problem and possible ways to improve performance. CMS has continued to discuss with the AOs their concerns as well as their performance in the area of evaluating health care facility safety from fire. CMS has engaged in rulemaking to update the Federal regulations to the 2012 edition of the LSC. While

we do not believe that the difference in LSC editions accounts for AOs' problems in identifying LSC deficiencies, this is an issue that AOs and the healthcare industry have raised and could affect the survey process. (See Graph 19.)

**Graph 19**  
**60-Day Validation Survey Results**  
**Comparison between All Other Conditions of Participation (CoPs) Cited and Physical Environment (PE) for Facility Types with Life Safety Code Requirements by Accrediting Organization**  
**Fiscal Year 2015**



#### Comparison of Deficiencies and Disparity Rates for Long-Term Care Hospitals and All Other Hospital Subtypes<sup>10</sup>

In 2010, CMS became concerned about the quality of care provided in LTCHs based on available SA survey findings. In the 2011 report to Congress, CMS reported on the analysis of mid-cycle validation surveys for 33 LTCHs. The Government Accountability Office (GAO) recommended in a September 2011 report that CMS strengthen oversight of LTCHs by, among other things, increasing the number of LTCH representative validation surveys and calculating a separate disparity rate for them.<sup>11</sup> (See Tables 24-26 and Graphs 20-24.) CMS attempted to increase the LTCH sample size for 60-day representative sample surveys. However, due to the scheduling of LTCH Medicare accreditation surveys by the AOs and the concentration of LTCHs in certain states, the ability of CMS to increase the sample size is limited. The need to

<sup>10</sup> LTCHs differ from other acute care hospitals in that they furnish extended medical and rehabilitative care to individuals with clinically complex problems, such as multiple acute or chronic conditions, that need hospital-level care for relatively extended periods. Other Hospital Subtypes are specific to acute care hospitals and do not include psychiatric hospitals.

<sup>11</sup> "Long-Term Care Hospitals: CMS Oversight is Limited and Should be Strengthened," GAO, GAO-11-810, September, 2011.

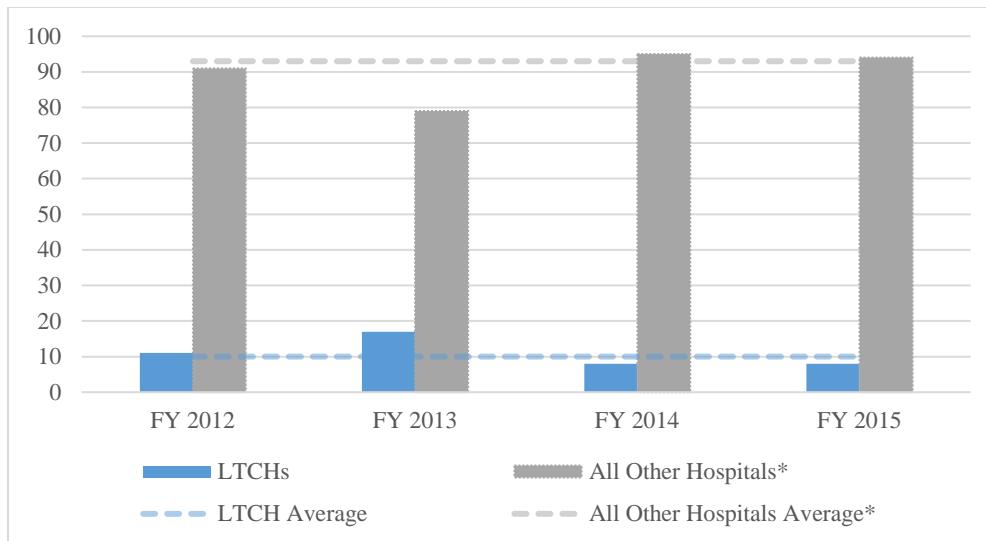
mobilize a State survey team within 60 days of AO surveys that are not entirely predictable is the main limiting factor, as the fixed surveyor capacity of SAs makes it impractical for SAs in those states to conduct a larger number of validation surveys. In FY 2015 the total number of Medicare participating LTCHs were 437 and the total number of Medicare participating hospitals minus the LTCHs were 3,495.

**Table 24**  
**Number of 60-Day Validation Surveys and Overall Disparity Rate**  
**Long-Term Care Hospitals (LTCHs) and All Other Hospital Subtypes**  
**Fiscal Years (FYs) 2012–2015**

	LTCHs				All Other Hospitals*				Average LTCHs	Average All Other Hospitals*
	FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015	FYs 2012–2015	FYs 2012–2015
60-Day Validation Sample Surveys	11	17	8	8	91	79	95	94	10	93
Overall Disparity Rate	45%	24%	38%	63%	45%	51%	38%	37%	43%	41%

\*All Other Hospital Subtypes are specific to acute care hospitals and do not include Psychiatric Hospitals.

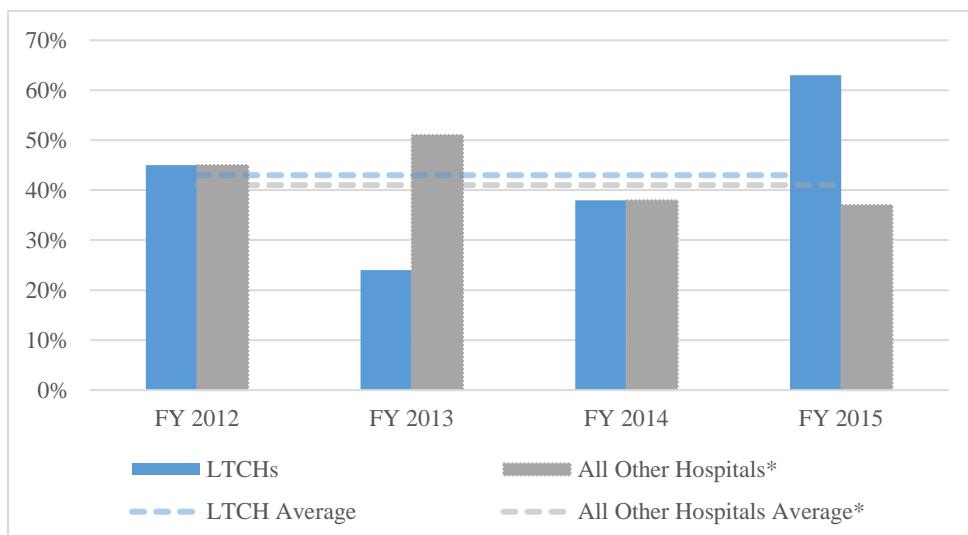
**Graph 20**  
**Number of 60-Day Validation Surveys and Averages**  
**Long-Term Care Hospitals (LTCHs) and All Other Hospital Subtypes**  
**Fiscal Years (FYs) 2012–2015**



\*All Other Hospital Subtypes are specific to acute care hospitals and do not include Psychiatric Hospitals.

\*Total number of Medicare participating LTCHs is 437 and the total number of Medicare participating hospitals minus the LTCHs is 3,495.

**Graph 21**  
**Overall Disparity Rates and Averages**  
**Long-Term Care Hospitals (LTCHs) and All Other Hospital Subtypes**  
**Fiscal Years (FYs) 2012–2015**



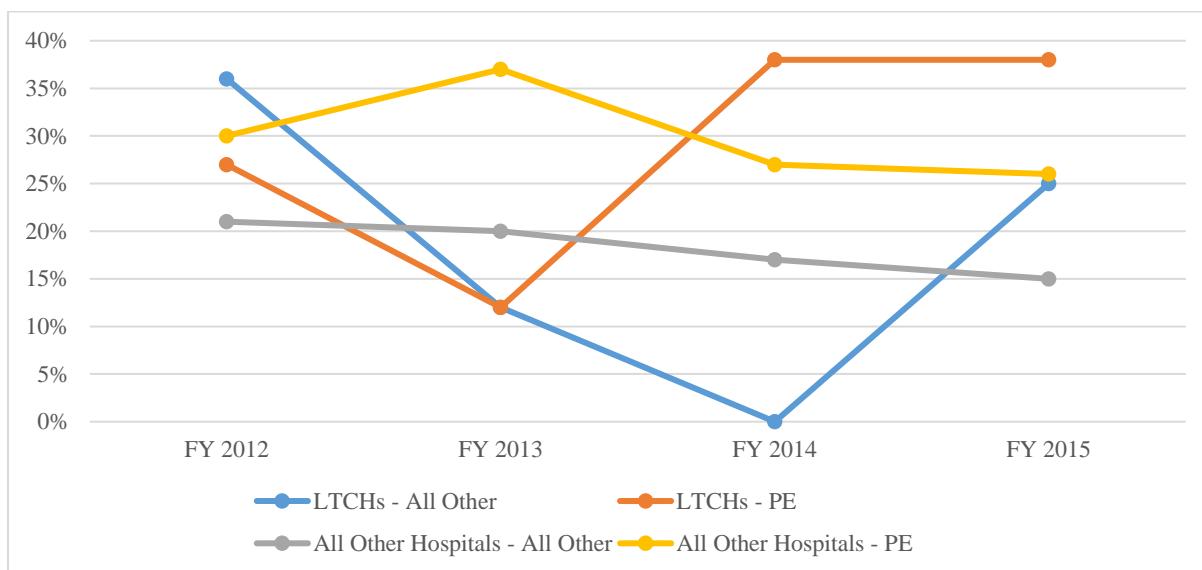
\*All Other Hospital Subtypes are specific to acute care hospitals and do not include Psychiatric Hospitals.

\*Total number of Medicare participating LTCHs is 437 and the total number of Medicare participating hospitals minus the LTCHs is 3,495.

**Table 25**  
**Comparison of 60-Day Health and Physical Environment Validation Survey Results for Long-Term Care Hospitals and All Other Hospital Subtypes**

	LTCHs All Other Conditions				LTCHs PE				All Other Hospitals All Other Conditions				All Other Hospitals PE			
	FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015
SA Surveys with Condition-Level Deficiencies	8	5	1	3	6	2	3	3	41	34	22	22	57	31	26	24
AO Surveys with Missed Comparable Deficiencies	4	2	0	2	3	2	3	3	19	16	16	14	27	29	26	24
Disparity Rate	36%	12%	0%	25%	27%	12%	38%	38%	21%	20%	17%	15%	30%	37%	27%	26%

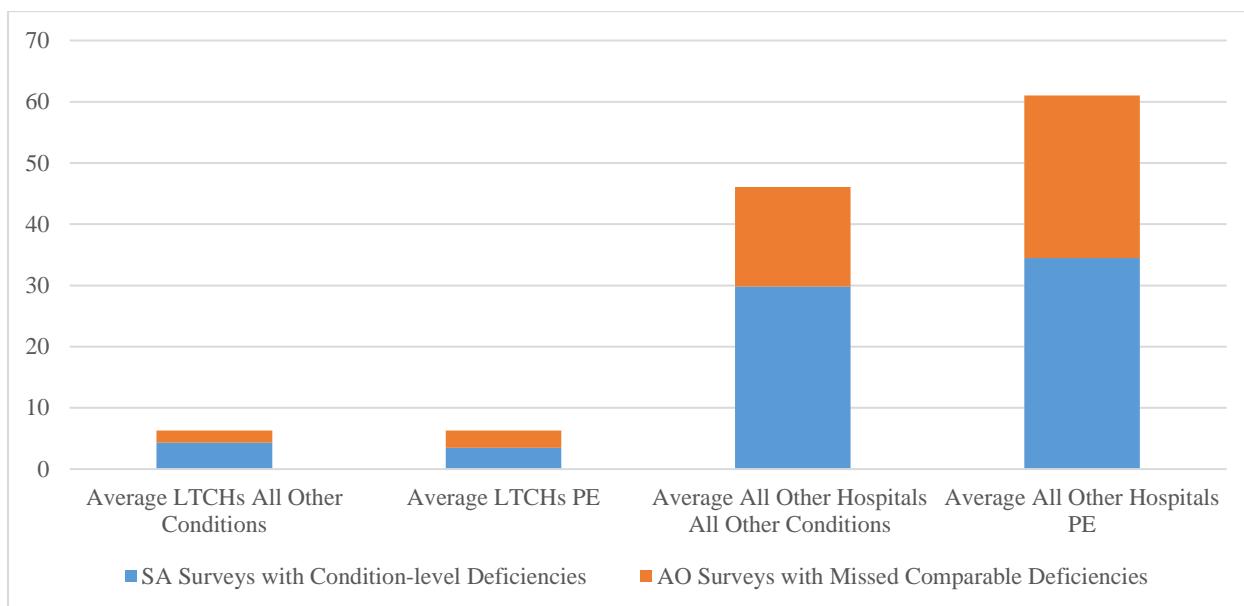
**Graph 22**  
**Comparison of 60-Day Health and Physical Environment Validation Survey Disparity Rate Results for Long-Term Care Hospitals and All Other Hospital Subtypes Fiscal Years (FYs) 2012–2015**



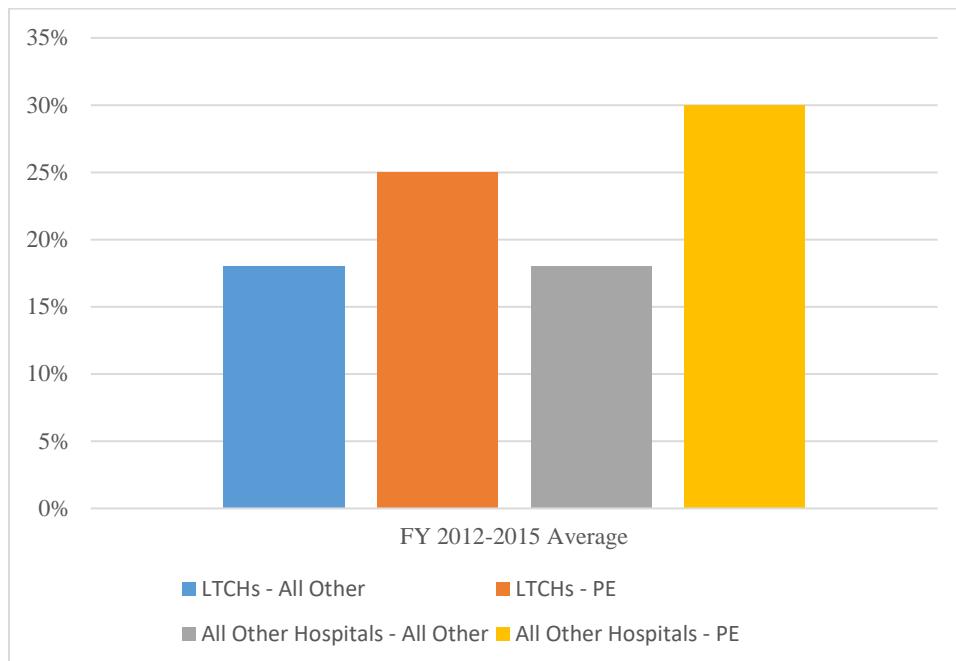
**Table 26**  
**Comparison of Averages**  
**60-Day Health and Physical Environment Validation Survey Results for Long-Term Care Hospitals and All Other Hospital Subtypes Fiscal Years (FYs) 2012–2015**

	FYs 2012–2015 Average LTCHs All Other Conditions	FYs 2012–2015 Average LTCHs PE	FYs 2012–2015 Average All Other Hospitals All Other Conditions	FYs 2012–2015 Average All Other Hospitals PE
SA Surveys with Condition-Level Deficiencies	4.3	3.5	29.8	34.5
AO Surveys with Missed Comparable Deficiencies	2	2.8	16.3	26.5
Disparity Rate	18%	25%	18%	30%

**Graph 23**  
**Comparison of Averages**  
**60-Day Health and Physical Environment Validation Survey Results for Long-Term Care Hospitals and All Other Hospital Subtypes Fiscal Years (FYs) 2012–2015**



**Graph 24**  
**Comparison of Averages**  
**60-Day Health and Physical Environment Validation Survey Disparity Rate Results for**  
**Long-Term Care Hospitals and**  
**All Other Hospital Subtypes**  
**Fiscal Years (FYs) 2012–2015**



From FYs 2012–2015, there is a 12 percent difference between the overall average disparity rates in LTCHs and all other hospital subtypes. However, when comparing the drivers of the average disparity rates, PE is the biggest driver in both LTCHs and all other hospital subtypes. Excluding PE, the most frequent disparate condition-level deficiencies for all other hospital subtypes in FY 2015 include Infection Control, Governing Body, and Patient Rights. The most frequent disparate condition-level deficiencies for LTCHs in FY 2015 were Infection Control, Organ, Tissue and Eye Procurement, Governing Body, and Patient Rights. In FY 2014, the most frequent disparate condition-level deficiencies for all other hospital subtypes were Governing Body, Infection Control, and QAPI. In FY 2014, PE was the only disparate condition-level deficiency for LTCHs.

## **SECTION 5: Baseline Analysis – Life Safety Code and Health & Safety Disparity Rates**

### **Background and Objectives**

As discussed in Section 4 of this report, a validation survey is a survey completed at a deemed facility by a SA within 60-days of the end date of an AO survey at the same facility. The results of the AO and SA surveys are compared, and a disparity rate is calculated. The disparity rate is the number of AO surveys where the AO did not cite deficiencies that were comparable to serious (condition-level) deficiencies identified during the SA surveys. This number is then divided by the total number of 60-day validation surveys conducted by the SA.

Since FY 2000, disparity rates have consistently been above an acceptable level for most of the program types. The PE condition, specifically LSC requirements, has consistently been the largest driver of the disparity rate for those program types with LSC requirements. This points to limitations in the AO's ability to identify non-compliance with the Medicare CoPs and CfCs LSC requirements.

The objective of this health and safety and LSC analysis is to identify the top categories that are most significantly influencing the disparity rate, identify potential root causes, and present recommendations for minimizing the overall disparity rate.

### **Methodology**

CMS compares the SA validation survey condition-level deficiency citations to the AO survey findings. Separate validation summary reports are then generated for the Health and Safety CoPs, and the PE conditions cited by the SAs. The Health and Safety summary report identifies each SA CoP finding and also identifies the comparable and non-comparable AO deficiency citations. If the AO has comparable findings to all of the identified SA findings, then the survey is determined to be a comparable survey. However, if the AO does not identify a comparable deficiency for all of the SA cited deficiencies, the survey is determined to be a disparate survey.

The PE summary report is similar to the Health and Safety summary report, but the PE summary report identifies and compares LSC categories and PE CoP requirements. If the AO has comparable findings to the identified PE deficiencies and LSC Categories, then the survey is considered to be a comparable survey. If the AO does not identify the SA identified PE CoP and LSC Category deficiencies, then the survey is considered to be a disparate survey.

The data from the summary reports is collected and stored in a database for analysis. The database contains a record for each facility that identifies the AO, each separate CoP and LSC category identified by the SA, and if the AO cited a comparable deficiency. Reports are generated from the analysis of this data to develop individual summary sheets for each program type and for each AO and the program types in which they survey. These summary sheets note the following: 1) the number of validation surveys in the sample; 2) the number of CoPs cited in the validation surveys; 3) the number of surveys that were not comparable; 4) the overall disparity rate; 5) each CoP that was cited by the SA; 6) the number of facilities with the CoP

cited; 7) the number of matching surveys for each CoP; 8) the number of disparate surveys for each CoP; and 9) the individual CoP disparity rate.

As mentioned in Section 4 of this report, the overall disparity rate is determined by dividing the number of disparate surveys by the total number of validation surveys in the sample. Each individual CoP disparity rate is determined by dividing the number of disparate surveys with that individual CoP, by the total number of validation surveys in the sample. The LSC Category Disparity rate is determined by dividing the number of LSC Categories that were missed by the AO, by the total number of LSC Categories that were cited by the SA.

## **Limitations**

There are some factors outside the control of CMS that may influence the data and disparity rates resulting from the report calculations. The AO disparity rates are based on the number of validation surveys that have been performed for each AO and program type. The disparity rate is only one way to measure AO performance. In some instances, the validation sample size is too small to provide statistically valid data. For example, if only one validation survey was performed for a particular AO and program type and that validation survey was found to be disparate, the disparity rate would be 100 percent. In order to provide a statistically valid sample size, additional validation surveys are required for each AO and program type. There are a number of factors that play into the number of representative validation surveys that can be performed. While scheduling validation surveys, CMS must consider the number of deemed facilities by state, the targeted facilities on the AO schedule, the overall sample size that is being assigned to the state in any given month, the need to spread the survey workload over a year, and ensuring that any one state is not overloaded for any given month. Newly approved AOs also pose a challenge when it comes to increasing the sample size. Additionally, CMS resource and budget constraints, as well as state resources, both budget and human resources, may prohibit the ability to perform a greater number of validation surveys for a statistically valid sample.

The SA performs their validation survey within 60 days of the AO survey which may have an effect on the disparate findings. During the 60-day gap between the AO and SA survey, some factors beyond CMS' control may have changed, making it difficult to provide an accurate comparison for the facility surveys.

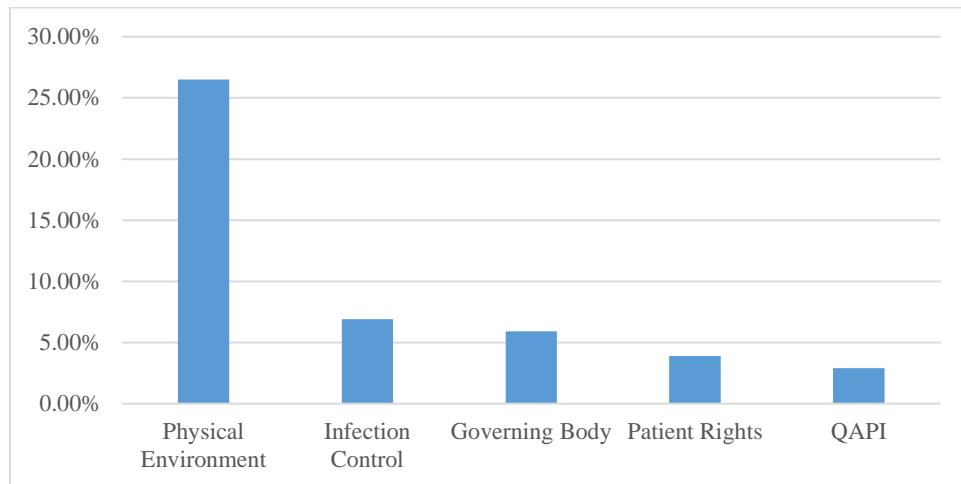
## **Findings**

The PE and Infection Control CoPs are the top disparate citations for hospitals, psychiatric hospitals, ASCs, and CAHs. The PE CoP was found to be in the top three disparate citations for all four of the program types and the Infection Control CoP was one of the top five disparate citations for ASCs, hospitals and psychiatric hospitals. The PE CoP contains multiple standards; however, 94 percent of the PE citations were comprised of the LSC standard within the CoP. Within the LSC standard categories, Fire/Smoke Barrier, Hazardous Areas, Sprinklers, Doors, and Means of Egress were the top deficiency citations not cited by AOs, with the Fire/Smoke Barrier noted in four of the program's top five missed citations. The other four LSC categories were found to be listed in the top five missed citations for three out of the four program types. The LSC category descriptions can be found in Appendix C.

The graphs below discuss, by program type, the top disparate CoPs, the top LSC disparity rates, and an overall depiction of the disparity rates for individual AOs. (See Graphs 4-19.)

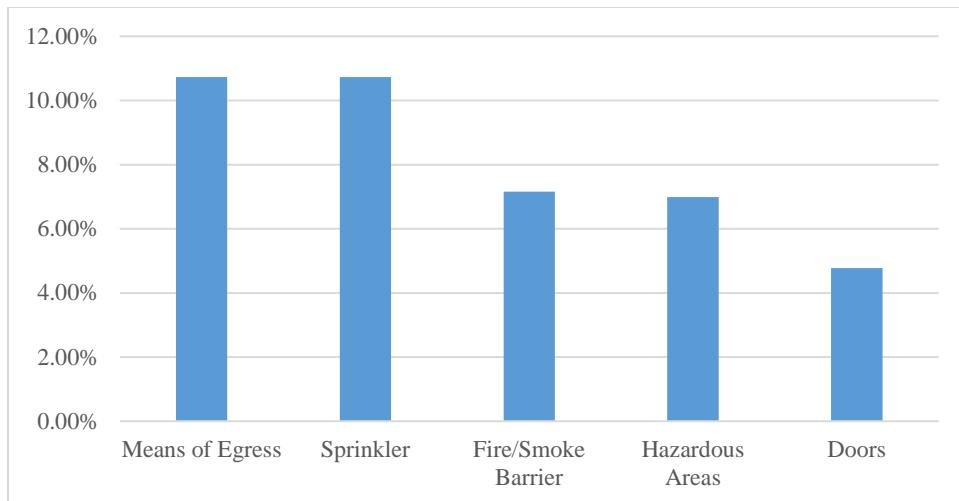
### **Hospital and Long Term Care Hospital (LTCH)**

**Graph 25**  
**Top Five Hospital and Long Term Care Hospital (LTCH) Disparity Rates**  
**Fiscal Year 2015**



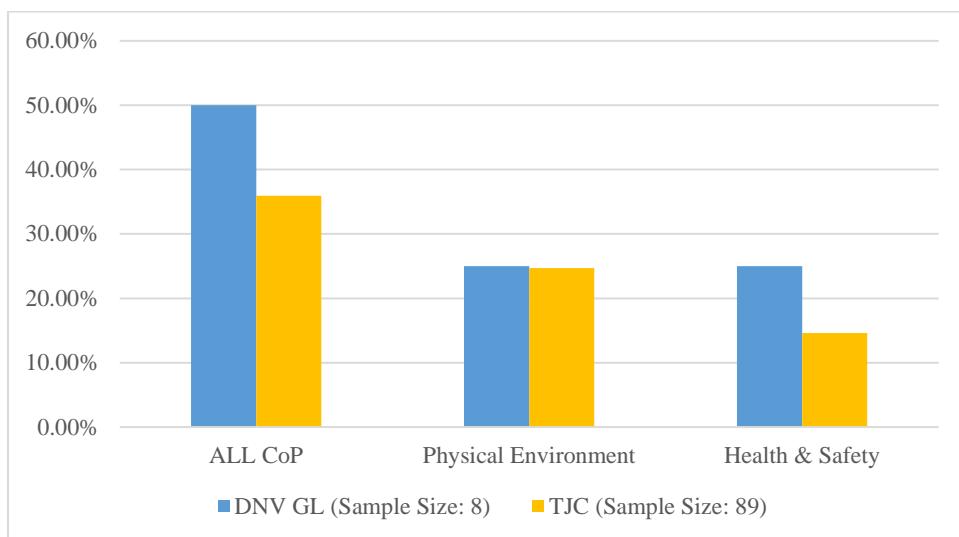
The hospital and LTCH samples consisted of 102 validation surveys in FY 2015. PE was identified as the number one disparate CoP and primary driver of the disparity rate. The SAs cited 27 condition-level PE citations. The AOs missed the same number of comparable PE citations resulting in a 26.5 percent disparity rate. The PE CoP was the number one disparate citation found for all of the AOs that had validation surveys where the PE CoP was cited. The AOs missed seven comparable deficiencies resulting in a 6.9 percent disparity rate. Twenty-seven of the 56 disparate findings can be attributed to the PE CoP which accounts for 48 percent of the hospital and LTCH disparate citations. Out of 56 total disparate findings, 47 of them were included in the top five disparate CoPs. The top five disparate CoPs make up 84 percent of all hospital and LTCH disparate findings. The overall disparity rate for hospitals and LTCHs was 39 percent.

**Graph 26**  
**Top Five Hospital and Long Term Care Hospital (LTCH)**  
**Life Safety Code (LSC) Category Disparity Rates**  
**Fiscal Year 2015**



Out of 102 hospital and LTCH validation surveys, 587 LSC category citations were cited by the SAs. The top two most frequently cited LSC categories were Means of Egress, with 87 SA citations, and Sprinkler, with 84 SA citations. The AOs missed 63 comparable citations for each category, resulting in a 10.7 percent LSC category disparity rate. A total of 237 missed LSC category citations comprised the top five disparate LSC categories, resulting in 66 percent missed LSC category citations for hospitals and LTCHs.

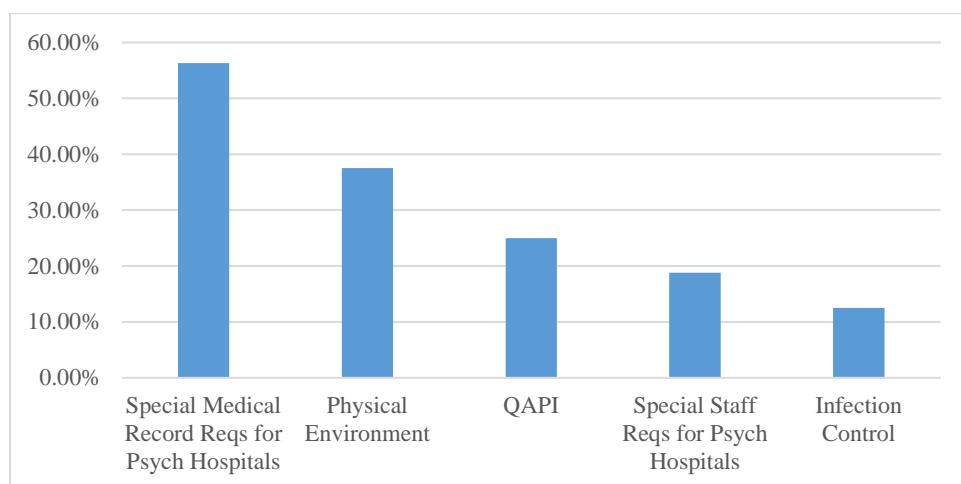
**Graph 27**  
**Hospital and Long Term Care Hospital (LTCH) Disparity Rates**  
**by Accrediting Organization (AO)**  
**Fiscal Year 2015**



There were 4, 1, 8, and 89 validation surveys performed for AOA/HFAP, CIHQ, DNV GL, and TJC respectively for hospitals and LTCHs. There were no validation surveys performed for AOA/HFAP that had Health and Safety CoPs cited and there were no validation surveys performed for CIHQ that had PE CoPs cited; therefore, CIHQ and AOA/HFAP were not included in this graph due to the limited number of validation surveys performed. Note: Reliable comparisons that can be made between DNV GL and TJC findings are limited based on the significant difference in validations sample survey sizes, 8 and 89 respectively.

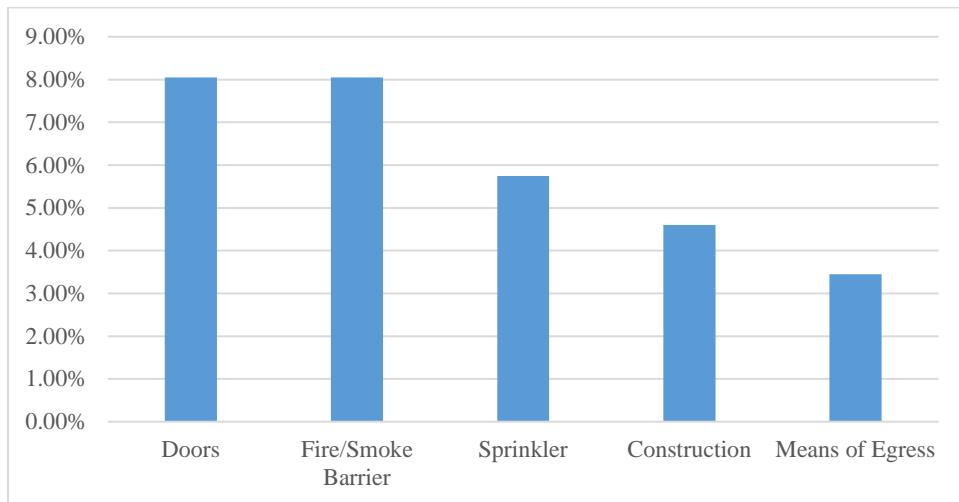
## **Psychiatric Hospital**

**Graph 28**  
**Top Five Psychiatric Hospital Disparity Rates**  
**Fiscal Year 2015**



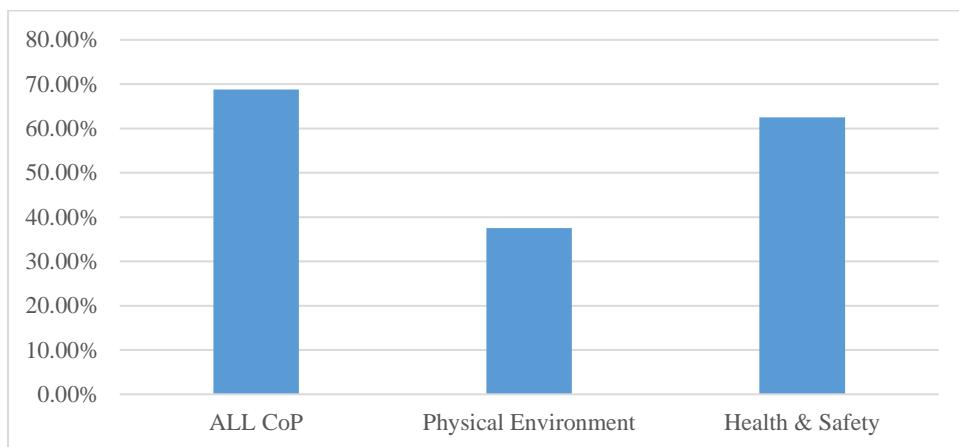
The psychiatric hospital sample consisted of 16 validation surveys in FY 2015. TJC is the only AO with a CMS-approved psychiatric hospital Medicare accreditation program. Special Medical Record Requirements for psychiatric hospitals was the number one disparate CoP. The SAs cited 14 condition-level citations. TJC missed nine comparable deficiencies resulting in a 56 percent disparity rate. PE was the next most frequently cited SA condition, with six SA condition-level citations. There were six validation surveys performed by the SA in which PE CoPs were cited and TJC did not have any comparable surveys for PE citations resulting in a 37.5 percent disparity rate. The overall disparity rate for psychiatric hospitals was 69 percent.

**Graph 29**  
**Top Five Psychiatric Hospital**  
**Life Safety Code (LSC) Category Disparity Rates**  
**Fiscal Year 2015**



Out of 16 psychiatric validation surveys, 87 LSC category citations were cited by the SAs. The top two most frequently cited LSC categories were Doors, with eight SA citations, and Fire/Smoke Barrier, with 18 SA citations. TJC missed seven comparable citations for each category, resulting in an eight percent LSC category disparity rate. A total of 26 missed LSC category citations comprised the top five disparate LSC categories, resulting in 72 percent missed LSC category citations for psychiatric hospitals.

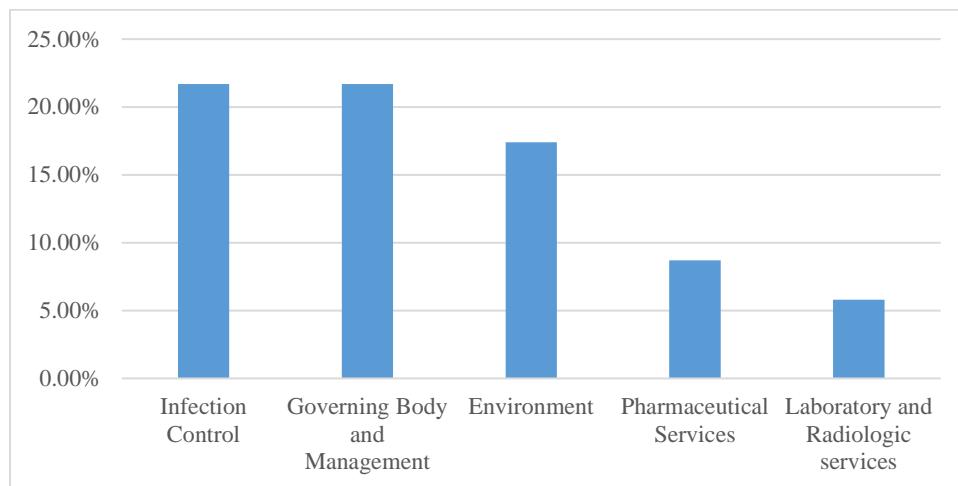
**Graph 30**  
**Psychiatric Hospital Disparity Rates**  
**by Accrediting Organization**  
**Fiscal Year 2015**



Sixteen psychiatric validation surveys were performed in FY 2015. The overall disparity rate for TJC was 68.75 percent, the PE disparity rate was 37.5 percent, and the Health and Safety disparity rate was 62.5 percent for Psychiatric Hospitals.

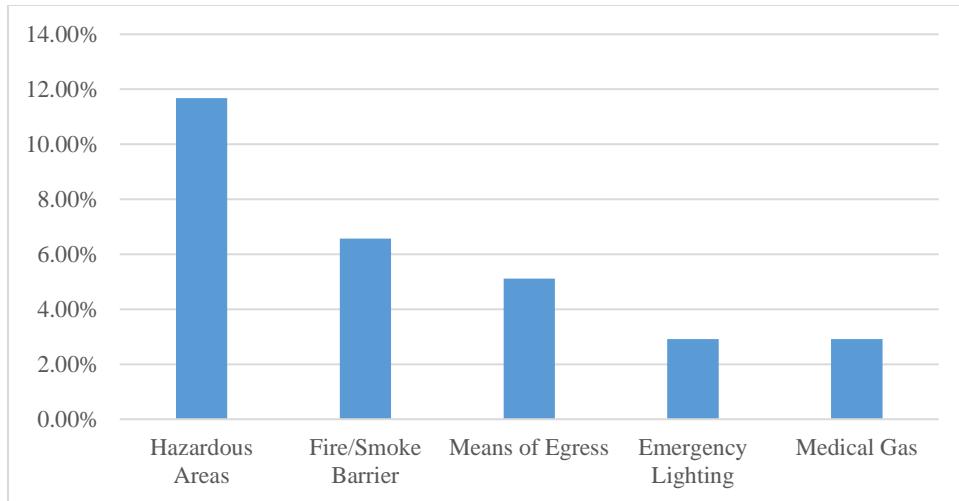
## Ambulatory Surgery Centers (ASCs)

**Graph 31**  
**Top Five Ambulatory Surgery Center (ASC) Disparity Rates**  
**Fiscal Year 2015**



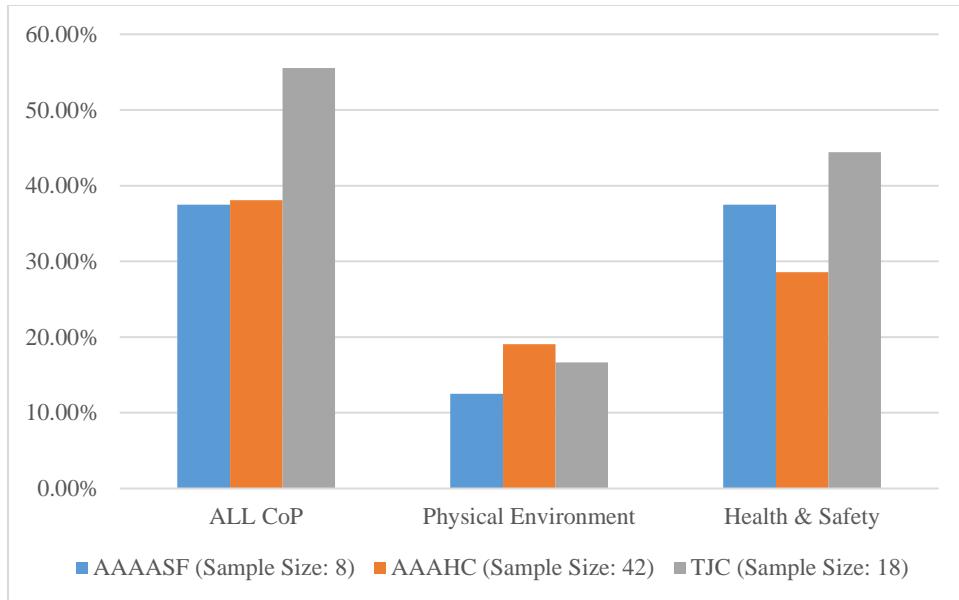
The ASC sample consisted of 69 validation surveys in FY 2015. Infection Control and Governing Body and Management were identified as the top two disparate CoPs. The SAs cited 23 condition-level Infection Control citations and 21 Governing Body and Management citations. For each of the CoPs, the AOs missed 15 comparable deficiencies resulting in a 21.7 percent disparity rate. The Infection Control CoP was the number one missed citation by AAAHC and it was equivalent for the number one missed citation for TJC along with the Governing Body and Management CoP. PE was the next most frequently cited disparate CoP. The SAs cited 13 condition-level citations. The AOs missed 12 comparable deficiencies resulting in a 17.4 percent disparity rate. The top three disparate CoPs account for 42 of the 71 disparate findings for ASCs and 59 percent of all disparate ASC findings. AOA only had one validation survey performed for ASCs and the survey was found to be comparable. The overall disparity rate for ASCs was 42 percent.

**Graph 32**  
**Top Five Ambulatory Surgery Center (ASC)**  
**Life Safety Code (LSC) Category Disparity Rates**  
**Fiscal Year 2015**



Out of 69 ASC validation surveys, 137 LSC category citations were cited by the SAs. The most frequently cited LSC category was Hazardous Areas, cited 18 times by the SAs. The AOs missed 16 comparable citations resulting in an 11.68 percent LSC category disparity rate. The Hazardous Areas LSC category missed citations contribute to 33.3 percent of all of the missed citations. A total of 40 missed LSC category citations comprised the top five disparate LSC categories, resulting in 83 percent missed LSC category citations for ASCs.

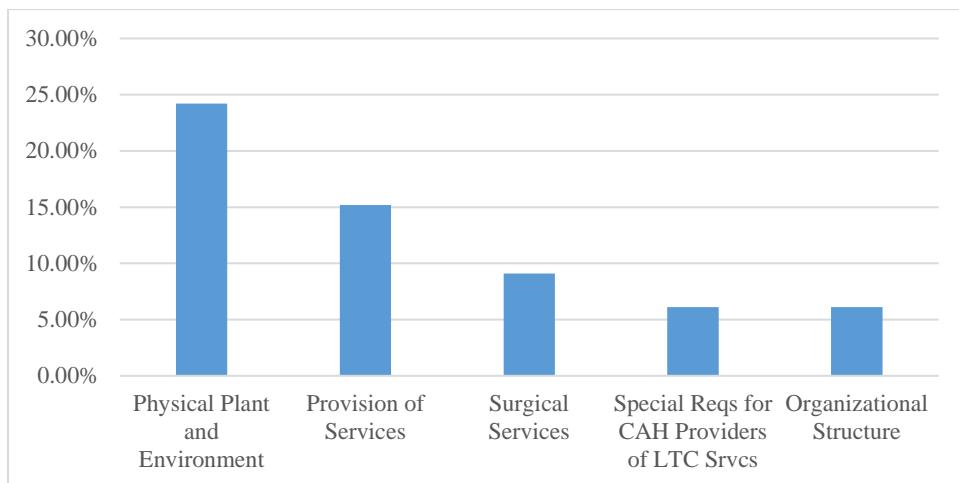
**Graph 33**  
**Ambulatory Surgery Center (ASC) Disparity Rates**  
**by Accrediting Organization (AO)**  
**Fiscal Year 2015**



There were 8, 42, 1, and 18 validation surveys performed for AAAASF, AAAHC, AOA/HFAP, and TJC respectively for ASCs. AOA/HFAP is not depicted in the above graph due to the single validation survey performed.

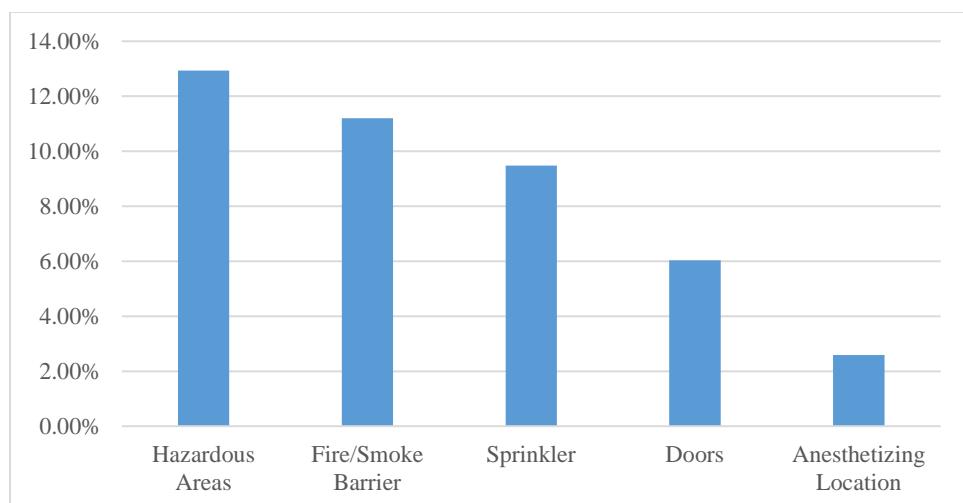
#### Critical Access Hospitals (CAHs)

**Graph 34**  
**Top Five Critical Access Hospital (CAH) Disparity Rates**  
**Fiscal Year 2015**



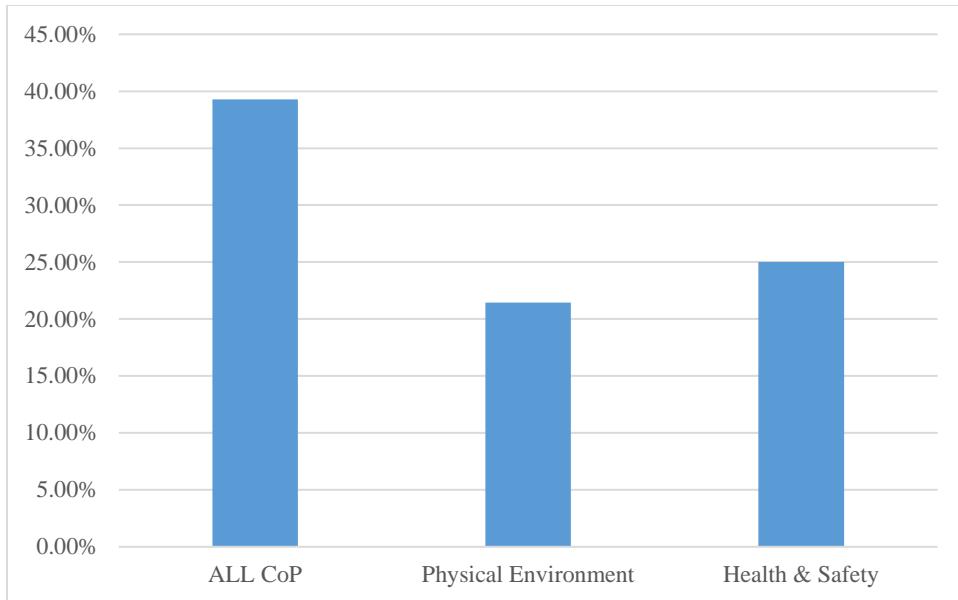
The CAH sample consisted of 33 validation surveys in FY 2015. Physical Plant and Environment was the number one disparate CoP. The SAs cited 10 Physical Plant and Environment citations. The AOs missed eight comparable deficiencies resulting in a 24.2 percent disparity rate. The number one disparate CoP citation for DNV GL and TJC was the Physical Plant and Environment condition while the Provision of Services CoP was the second highest disparity for TJC. Twenty of 25 disparate findings accounted for the top five disparate CoPs. The top five disparate CoP citations make up 80 percent of all CAH disparate findings. The overall disparity rate for CAHs was 45 percent with the Physical Plant and Environment CoP having the highest individual disparity rate of 24 percent.

**Graph 35**  
**Top Five Critical Access Hospital (CAH)**  
**Life Safety Code (LSC) Category Disparity Rates**  
**Fiscal Year 2015**



Out of 33 CAH validation surveys, 116 LSC category citations were cited by the SAs. Hazardous Areas was the most frequently cited LSC category, with 15 SA citations. The AOs missed the 15 comparable LSC category citations, resulting in a 12.93 percent disparity rate. The Fire/Smoke Barrier category was the second highest missed category for TJC while it was the number one missed citation for DNV GL. A total of 49 missed LSC category citations comprised the top five disparate LSC categories, resulting in 82 percent missed LSC category citations for CAHs.

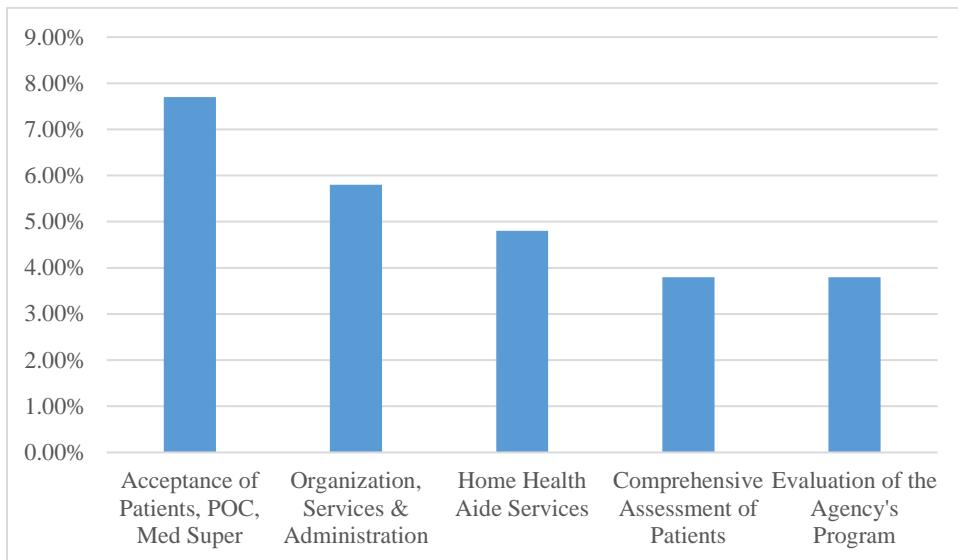
**Graph 36**  
**Critical Access Hospital (CAH) Disparity Rates**  
**by Accrediting Organization**  
**Fiscal Year 2015**



There were 3, 2, and 28 validation surveys performed for AOA/HFAP, DNV GL, and TJC respectively for CAHs. There were no validation surveys performed for DNV GL that had Health and Safety CoPs cited and there were no validation surveys performed for AOA/HFAP that had PE CoPs cited. DNVGL and AOA/HFAP were not included in this graph due to the limited number of validation surveys performed.

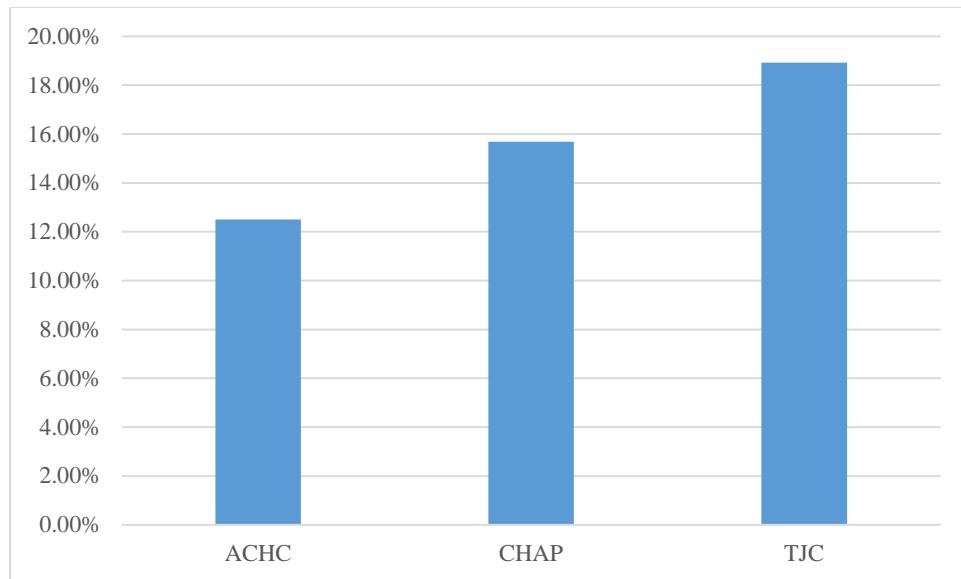
## **Home Health Agency (HHA)**

**Graph 37**  
**Top Five Home Health Agency (HHA) Disparity Rates**  
**Fiscal Year 2015**



The HHA sample consisted of 104 validation surveys in FY 2015. HHAs do not have any PE or LSC requirements. Acceptance of Patients, Plan of Care and Medical Supervision was the number one disparate CoP identified for HHAs during that time. The SAs cited 15 condition-level citations. The AOs missed eight comparable deficiencies, resulting in a 7.7 percent disparity rate. This CoP was the number one disparate citation for CHAP and ACHC, while it was the number two disparate CoP for TJC. Twenty-seven out of 40 disparate findings accounted for the top five disparate CoPs. The top five disparate CoPs make up 68 percent of all HHA disparate CoP findings. The overall disparity rate for HHAs was 16 percent with the Acceptance of Patients, Plan of Care & Medical Supervision CoP having the highest individual disparity rate of 8 percent.

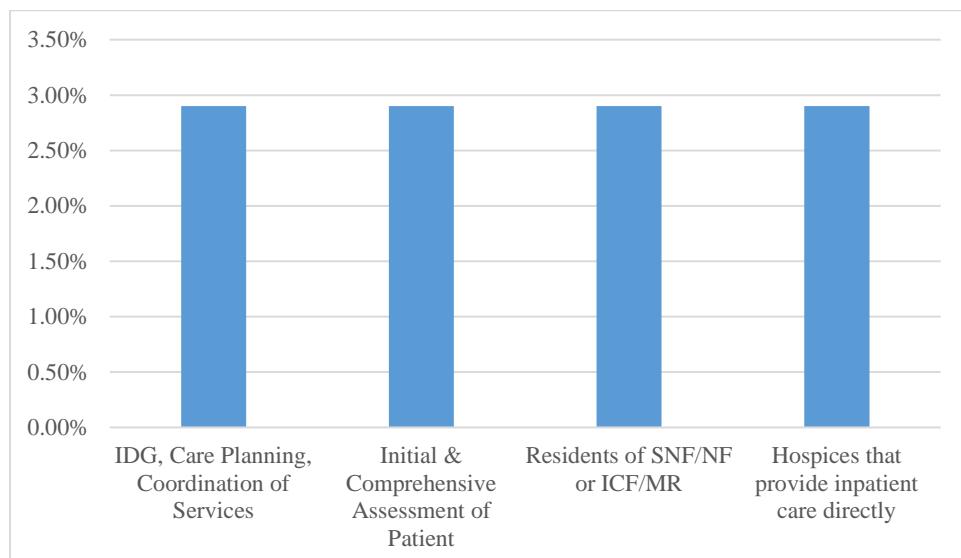
**Graph 38**  
**Home Health Agency (HHA) Health and Safety Disparity Rates**  
**by Accrediting Organization (AO)**  
**Fiscal Year 2015**



There were 16, 51, and 34 validation surveys performed for ACHC, CHAP, and TJC respectively for HHAs.

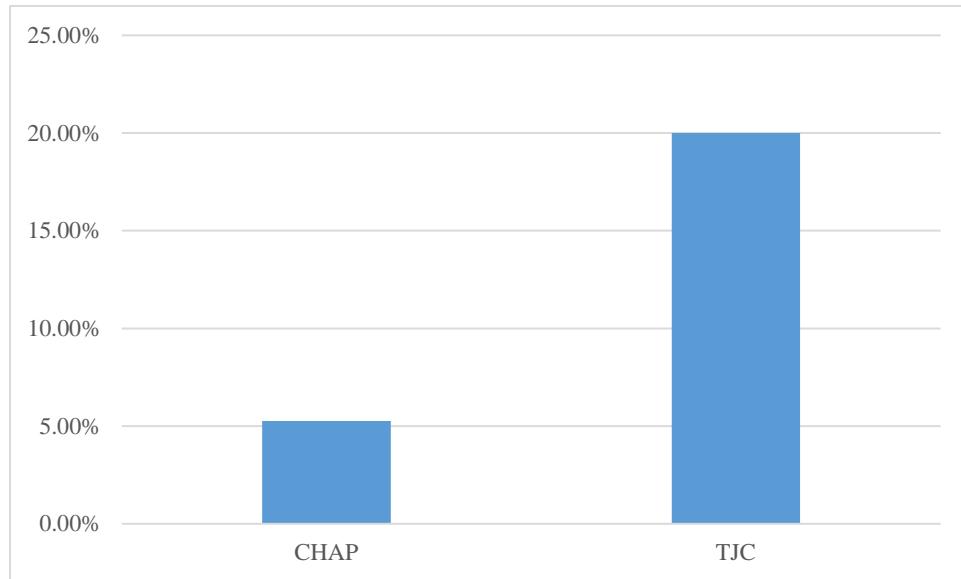
### Hospice

**Graph 39**  
**Top Five Hospice Disparity Rates**  
**Fiscal Year 2015**



The hospice sample consisted of 34 validation surveys in FY 2015. Hospice facilities do not have any PE or LSC requirements. In this sample, only four surveys were cited for condition-level deficiencies. Interdisciplinary Group (IDG)/Care Planning/Coordination of Services was the most frequently cited CoP, with two SA condition-level citations. Initial & Comprehensive Assessment of Patient, residents of skilled nursing facilities (SNFs)/nursing facilities (NFs) or Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IDs, and hospices that provide inpatient care directly had one SA condition-level citation each. The AOs missed one comparable deficiency for each of the four CoPs, resulting in a 2.9 percent disparity rate. The only two cited CoPs for TJC were hospices that provide inpatient care directly (one citation) and residents of SNFs/NFs or ICF/IDs (one citation) and both of these citations were missed by TJC. The two CoPs cited for CHAP were IDG/ Care Planning/Coordination of Services (two citations) and Initial/Comprehensive Assessment of Patient (one citation). CHAP had one comparable finding for IDG/Care Planning/Coordination of Services and no comparable findings for the Initial and Comprehensive Assessment of Patient CoP. The overall hospice disparity rate was nine percent and each of the four CoPs displayed in the graph had an equal disparity rate of three percent.

**Graph 40**  
**Hospice Health and Safety Disparity Rates**  
**by Accrediting Organization (AO)**  
**Fiscal Year 2015**



There were 5, 19, and 10 validation surveys performed for ACHC, CHAP, and TJC respectively for the hospice program. There were no validation surveys performed for ACHC that had condition-level deficiencies cited. ACHC had a zero percent disparity rate for the hospice program.

## Conclusion

CMS has identified the top disparate CoPs and LSC Categories. The PE/Environment is one of the leading disparate conditions, accounting for 16 to 48 percent of all disparate surveys,

throughout all of the program types with the exception of HHAs and hospices. The largest portion of the PE/Environment CoP findings are the LSC. The SA and AO LSC survey validation findings are divided into various categories for analysis and comparison, yielding the top five disparate LSC categories. Fire/Smoke Barrier, one of the FY 2015 top five disparate LSC categories, is common to each program type with the exception of HHAs and hospices. The remaining four of the top five categories: Hazardous Areas, Sprinklers, Doors, and Means of Egress, were all found in the top five disparate LSC findings for three of the four separate program types. Hazardous Areas was the number one disparate finding for CAHS and ASCs and number four for hospitals and LTCHs. Sprinklers was the number two disparate finding for hospitals and LTCHs and number three for CAHs and psychiatric hospitals. Doors was the number one disparate finding for psychiatric hospitals, number four for CAHs, and number five for hospitals and LTCHs. Means of Egress was the number one disparate finding for hospitals and LTCHs, number three for ASCs, and number five for psychiatric hospitals. Infection Control, a Health and Safety CoP is also among the leading disparate conditions across hospitals and LTCHs, psychiatric hospitals, and ASCs. Among the individual AOs for hospitals and LTCHs, DNV GL has the highest Health and Safety disparity rate and overall CoP disparity rate. DNV GL also has the highest Physical Environment disparity rate for CAHs and hospitals. TJC has the highest Health and Safety disparity rates for ASCs, CAHs, HHAs and hospices and the highest overall CoP disparity rate for ASCs and CAHs. AAAHC has the highest Physical Environment disparity rate for ASCs.

## **Recommendations**

### AOs need to focus their interventions on their top disparate CoPs

The AOs need to develop interventions to impact their high-volume disparate CoPs. If the AOs were to focus on the top disparate CoPs with the highest disparity rates, they would have an opportunity to positively impact their disparity rate. For example, if the AOs would address the top five disparate CoPs for hospitals, they could potentially eliminate 48 percent of the disparate citations.

CMS will monitor the disparity rates on a quarterly basis concurrent with the FY in which the validation surveys are conducted. Trending of the CoPs involved as well as identification of the problem facilities will be discussed on the individual monthly AO liaison calls. Action plans to address identified trends and disparity rates will be required of each AO.

Detailed information for each program type and AO for Section 7 of this report can be found in Appendix B of this report.

## **SECTION 6: Centers for Medicare & Medicaid Services Improvements**

The volume of facilities that participate in the Medicare programs through accreditation from a CMS-approved accreditation program continued to grow in FY 2015. Currently, 40 percent (12,415 facilities) of all Medicare-participating facilities that have an approved accreditation program option demonstrate compliance with the Medicare requirements and participate in the Medicare program via their deemed status. There are currently nine CMS-recognized AOs and 21 approved accreditation programs.

CMS has worked to enhance systems and processes to ensure a robust and consistent approach to its monitoring and oversight of CMS-recognized AO performance and activities of their approved accreditation programs. In FY 2015, CMS focused on the following key areas in order to continue to refine and maintain an effective oversight infrastructure:

- CMS/AO Communication and Relationship Building
- AO Education
- Standards Update in Response to Changes in CMS Requirements
- Deemed Facility Data (See Section 2 for more information)
- AO Performance Measures (See Section 3 for more information)

### **Centers for Medicare & Medicaid/Accrediting Organization Communication and Relationship Building**

#### Communication

CMS continues its periodic meetings with recognized national AOs, including quarterly teleconferences. These meetings serve to foster communication between the AOs and CMS and serve as a forum to: discuss any issues as they arise; communicate and discuss regulatory changes; assure ongoing deemed facility compliance with Medicare conditions; and provide information and education for AO staff. CMS CO, RO staff, and individual AOs communicate on a weekly, if not daily, basis either by email or telephone to address a wide variety of issues, including, but not limited to: specific deemed facility deficiencies, certification issues, program operations, surveys, requirements, interpretation of regulations, and data.

#### Consultation

CMS increased opportunities for AOs as well as other stakeholders to provide input into the development of sub-regulatory guidance concerning Medicare standards and survey processes. AOs and other key stakeholders are provided the opportunity to review and provide comment on guidance prior to release. CMS has committed to ongoing consultation with the AOs and the stakeholders in an effort to improve the resulting guidance.

#### Accrediting Organization Education

CMS affords AO staff many opportunities for education. CMS provides detailed written and verbal feedback to the AOs as part of the deeming application and data review processes. This

feedback includes specific references to Medicare regulatory requirements as well as the SOM references and attachments. Formal education is provided periodically at the request of individual AOs. AOs are also provided the opportunity to send representatives to SA surveyor training and to participate in on-line SA surveyor training. Also, in FY 2015, CMS provided updates to the AO resource manual. This manual contains a wide variety of information on CMS requirements and expectations of AO performance.

#### Standards Update in Response to Changes in CMS Requirements

The final rule entitled, “Medicare and Medicaid Programs: Revisions to Deeming Authority Survey, Certification, and Enforcement Procedures,” published in the *Federal Register* on May 22, 2015, contains revisions to the survey, certification, and enforcement procedures related to CMS oversight of national AOs (80 FR 29795). The final rule can be accessed at <https://www.gpo.gov/fdsys/pkg/FR-2015-05-22/pdf/2015-12087.pdf>. The revisions implement certain provisions under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The revisions also clarify and strengthen our oversight of AOs that apply for and are granted recognition and approval of an accreditation program in accordance with the statute. The rule extends some provisions, which are applicable to Medicare-participating providers, to Medicare-participating suppliers subject to certification requirements and clarifies the definition of immediate jeopardy.

An LSC SharePoint site has been implemented to replace the previous method for AO submission and RO review, and approval or denial of LSC Waiver and Fire Safety Evaluation System (FSES) requests. The LSC SharePoint site is an organized repository of documents that is accessible to AOs, ROs, CO, and contract staff to manage and inventory all LSC Waiver and FSES requests, and supporting documents submitted to CMS by AOs on behalf of their accredited facilities. Contract staff will maintain and monitor the site and provide support to RO staff. Meetings with ROs and AOs have been held to identify issues and opportunities for improvement and the LSC SharePoint site continues to be modified to increase functionality and usability.

## **SECTION 7: Clinical Laboratory Improvement Amendments Validation Program**

### **Introduction**

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) expanded survey and certification of clinical laboratories from Medicare-participating and interstate commerce laboratories to all facilities testing human specimens for health purposes, regardless of location. CMS regulates all laboratory testing (whether provided to beneficiaries of CMS programs or to others), including those performed in physicians' offices, for a total of 243,706 facilities at the beginning of CY 2015. The CLIA standards are based on the complexity of testing; thus, the more complex the test is to perform, the more stringent the requirements. There are three categories of tests: waived, moderate, and high complexity. Laboratories that perform only waived tests are not subject to the quality standards under CLIA or routine oversight.

Laboratories which perform moderate and high complexity testing are subject to routine on-site surveys. These laboratories have a choice of the agency they wish to survey their laboratory. They can select CMS via the SAs or a CMS-approved AO. CMS partners with the states to certify and inspect approximately 18,524 laboratories every two years. CMS-approved AOs conduct on-site surveys of an additional 16,432 laboratories also every two years. Data from these inspections reflect significant improvements in the quality of testing over time. The CLIA program is 100 percent user-fee financed and is jointly administered by three Health and Human Service (HHS) components: (1) CMS manages the financial aspects, contracts and trains state surveyors to inspect labs, and oversees program administration including enrollment, fee assessment, regulation and policy development, approval of AOs, exempt states and proficiency testing providers, certificate generation, enforcement and data system design; (2) the Centers for Disease Control and Prevention (CDC) provides research and technical support, and coordinates the Secretary's Clinical Laboratory Improvement Advisory Committee (CLIAC); and (3) the Food and Drug Administration (FDA) performs test categorization.

This report on the Clinical Laboratory Improvement Validation Program covers the evaluations of FY 2015 performance by the seven AOs approved by CMS under CLIA. The seven organizations are:

- AABB
- American Association for Laboratory Accreditation (A2LA)
- American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)
- American Society for Histocompatibility and Immunogenetics (ASHI)
- College of American Pathologists (CAP)
- COLA
- The Joint Commission (TJC)

CMS appreciates the cooperation of all the organizations in providing their inspection schedules and results. While an annual performance evaluation of each approved AO is required by law, we also see this as an opportunity to present information about, and dialogue with, each

organization as part of our mutual interest in improving the quality of testing performed by clinical laboratories across the nation.

## **Legislative Authority and Mandate**

Section 353 of the Public Health Service Act, as amended by CLIA, requires any laboratory that performs testing on human specimens for health purposes to meet the requirements established by the CLIA statute and regulations and have in effect an applicable certificate. Section 353 further provides that a laboratory meeting the standards of an approved AO may obtain a CLIA Certificate of Accreditation. Under the CLIA Certificate of Accreditation, the laboratory is not routinely subject to direct Federal oversight by CMS. Instead, the laboratory receives an inspection by the AO in the course of maintaining its accreditation, and by virtue of this accreditation, is “deemed” to meet the CLIA requirements. The CLIA requirements pertain to quality assurance and quality control programs, records, equipment, personnel, proficiency testing, and other areas to assure accurate and reliable laboratory examinations and procedures.

In Section 353(e)(2)(D), the Secretary is required to evaluate each approved AO by inspecting a sample of the laboratories they accredit and “such other means as the Secretary determines appropriate.” In addition, section 353(e)(3) requires the Secretary to submit to Congress an annual report on the results of the evaluation. This report is submitted to satisfy that requirement.

Regulations implementing Section 353 are contained in 42 CFR Part 493 “Laboratory Requirements”. Subpart E of Part 493 contains the requirements for validation inspections, which are conducted by CMS or its agent to ascertain whether an accredited laboratory is in compliance with the applicable CLIA requirements. Validation inspections for clinical laboratories are conducted no more than 90 days after the AO’s inspection, on a representative sample basis or in response to a complaint. The results of these validation inspections provide:

- On a laboratory-specific basis, insight into the effectiveness of the AO’s standards and accreditation process; and
- In the aggregate, an indication of the organization’s capability to assure laboratory performance equal to or more stringent than that required by CLIA.

The CLIA regulations, at 42 CFR §493.575, provide that if the validation inspection results over a one-year period indicate a rate of disparity<sup>12</sup> of 20 percent or more between the findings in the AO’s results and the findings of the CLIA validation surveys, CMS will re-evaluate whether the AO continues to meet the criteria for an approved AO (also called “deeming authority”). Section 493.575 further provides that CMS has the discretion to conduct a review of an AO program if validation review findings, irrespective of the rate of disparity, indicate such widespread or systematic problems in the organization’s accreditation process that the AO’s requirements are no longer equivalent to CLIA requirements.

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<sup>12</sup> The methodology for the CLIA Rate of Disparity is calculated the same as in Figure 2 of this report. The only difference is that CLIA validation surveys are performed up to 90-days after an AO inspection instead of 60 days.

## **Validation Reviews**

The validation review methodology focuses on the actual implementation of an organization's accreditation program described in its request for approval. The AO's standards, as a whole, were approved by CMS as being equivalent to or more stringent than the CLIA condition-level requirements<sup>13</sup>. This equivalency is the basis for granting deeming authority.

In evaluating an organization's performance, it is important to examine whether the organization's inspection findings are similar to the CLIA validation survey findings. It is also important to examine whether the organization's inspection process sufficiently identifies, brings about correction, and monitors for sustained correction, laboratory practices and outcomes that do not meet their accreditation standards, so that equivalency of the accreditation program is maintained.

The organization's inspection findings are compared, case-by-case for each laboratory in the sample, to the CLIA validation survey findings at the condition level. If it is reasonable to conclude that one or more of those condition-level deficiencies were present in the laboratory's operations at the time of the organization's inspection, yet the inspection results did not note them, the case is a disparity. When all of the cases in each sample have been reviewed, the rate of disparity for each organization is calculated by dividing the number of disparate cases by the total number of validation surveys, in the manner prescribed by Section 493.2 of the CLIA regulations.

## **Number of Validation Surveys Performed**

As directed by the CLIA statute, the number of validation surveys should be sufficient to "allow a reasonable estimate of the performance" of each AO. A representative sample of more than 15,000 accredited laboratories received a validation survey in 2015. Laboratories seek and relinquish accreditation on an ongoing basis, so the number of laboratories accredited by an organization during any given year fluctuates. Moreover, many laboratories are accredited by more than one organization. Each laboratory holding a Certificate of Accreditation, however, is subject to only one validation survey for the AO it designates for CLIA compliance, irrespective of the number of accreditations it attains.

Nationwide, fewer than 500 of the accredited laboratories used AABB, A2LA, AOA/HFAP, or ASHI accreditation for CLIA purposes. Given these proportions, very few validation surveys were performed in laboratories accredited by those organizations. The overwhelming majority of accredited laboratories in the CLIA program used their accreditation by COLA, CAP or TJC, thus the sample sizes for these organizations were larger. The sample sizes are roughly proportionate to each organization's representation in the universe of accredited laboratories; however, true proportionality is not always possible due to the complexities of scheduling.

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<sup>13</sup> A condition-level requirement pertains to the significant, comprehensive requirements of CLIA, as opposed to a standard-level requirement, which is more detailed and more specific. A condition-level deficiency is an inadequacy in the laboratory's quality of services that adversely affects, or has the potential to adversely affect, the accuracy and reliability of patient test results.

The number of validation surveys performed for each organization is specified below in the summary findings for the organization.

### **Results of the Validation Reviews of Each Accreditation Organization**

#### **AABB**

Rate of disparity: zero percent

In FY 2015, approximately 209 laboratories used their AABB accreditation for CLIA program purposes. Validation surveys were conducted in 12 AABB accredited laboratories. No condition-level deficiencies were cited in any of the validation surveys. When a validation survey results in compliance with the CLIA condition-level requirements, as is the case with the AABB accredited laboratories this year, the result is a disparity rating of zero (no disparity). We commend the AABB for its history of zero percent disparity in 16 out of the past 20 validation reviews.

#### **American Association for Laboratory Accreditation (A2LA)**

Rate of disparity: NA

On March 25, 2014, A2LA was the seventh AO to receive deeming authority by CMS. Due to the low number of deemed facilities, only two validation surveys were conducted. Therefore, no additional data are reported.

#### **American Osteopathic Association/ Healthcare Facilities Accreditation Program (AOA/HFAP)**

Rate of disparity: 14 percent

For CLIA purposes, approximately 127 laboratories used their AOA/HFAP accreditation. Validation surveys were conducted in seven AOA/HFAP-accredited laboratories. Condition-level deficiencies were cited in one validation survey. AOA/HFAP noted comparable findings for none of the CLIA condition-level deficiencies cited; thus, there was one disparate case yielding a disparity rate of 14 percent.

#### **American Society for Histocompatibility and Immunogenetics (ASHI)**

Rate of disparity: zero percent

Approximately 111 laboratories used their ASHI accreditation for CLIA purposes. A validation survey was conducted in six ASHI-accredited laboratories. No condition-level deficiencies were cited in any of the validation surveys. When a validation survey results in compliance with the CLIA condition-level requirements, as is the case with the ASHI accredited laboratories this year, the result is a disparity rating of zero (no disparity). We commend the ASHI for its history of zero percent disparity in 19 out of the past 20 validation reviews.

## **COLA**

Rate of disparity: 9 percent

In FY2015, 6,667 laboratories used their COLA accreditation for CLIA program purposes. A total of 182 validation surveys were conducted in COLA-accredited laboratories. One survey was removed from the review pool for administrative reasons. Of the remaining 181, 22 laboratories were cited with condition-level deficiencies. In five of those laboratories, COLA findings were comparable to all of the CLIA condition-level deficiencies cited. In the remaining 17 laboratories, however, COLA noted comparable findings for only some or none of the CLIA condition-level deficiencies cited; thus, there were 17 disparate cases yielding a disparity rate of 9 percent.

## **College of American Pathologists (CAP)**

Rate of disparity: 14 percent

In FY2015, 6,183 laboratories used their CAP accreditation for CLIA program purposes. A total of 98 validation surveys were conducted in CAP-accredited laboratories. Two surveys were removed from the review pool for administrative reasons. Of the remaining 96 validation surveys, 13 laboratories were cited with CLIA condition-level deficiencies. In all 13, CAP noted comparable findings for only some or none of the CLIA condition-level deficiencies cited; thus, there were 13 disparate cases for a disparity rate of 14 percent.

## **The Joint Commission (TJC)**

Rate of disparity: 12 percent

In FY2015, 2,231 laboratories used their TJC accreditation for CLIA program purposes. During this validation period, a total of 58 validation surveys were conducted in TJC accredited laboratories. Nine laboratories were cited with CLIA condition-level deficiencies. In two of those laboratories, TJC findings were comparable to all of the CLIA condition-level deficiencies cited. In seven laboratories, TJC noted comparable findings for only some or none of the CLIA condition-level deficiencies cited; thus, there were seven disparate cases yielding a disparity rate of 12 percent.

**Table 27**  
**Validation Survey Results for Clinical Laboratories**  
**Fiscal Year 2015**

<b>Number of</b>	<b>AABB</b>	<b>A2LA</b>	<b>AOA</b>	<b>ASHI</b>	<b>COLA</b>	<b>CAP</b>	<b>TJC</b>	<b>Total</b>
Accredited Labs	209	2	127	111	6,667	6,183	2,231	15,530
Validation Surveys	12	2	7	6	182	98	58	365
Surveys with Condition-Level Deficiencies	0	2	1	0	22	13	9	47
Surveys with One or More Condition-Level Deficiencies Missed by AO	0	1	1	0	17	13	7	39
<b>Disparity Rate</b>	<b>0%</b>	N/A *	<b>14.3%</b>	<b>0%</b>	<b>9.4%</b>	<b>13.5%</b>	<b>12.1%</b>	<b>14.2%</b>

\*N/A: When a minimum sample size of five is not achieved for an AO, no data is reported given the lack of statistical significance.

## Conclusion

CMS has performed this statutorily mandated validation review in order to evaluate and report to Congress on the performance of the seven laboratory AOs approved under CLIA. This endeavor is two-fold: to verify each organization's capability to assure laboratory performance equal to, or more stringent than, that required by CLIA ("equivalency"); and to gain insight into the effectiveness of the AO's standards and accreditation process on a laboratory-specific basis.

CMS recognizes that similarity of AO findings to CLIA validation survey findings is an important measure of the organization's capability to ensure and sustain equivalency and effectiveness of oversight. When an accredited laboratory's practices and outcomes fail to conform fully to the accreditation standards, it is important that the AO's inspection protocol sufficiently identifies the deficiencies, brings about correction, and monitors for sustained compliance, so that the laboratory is again in full conformance with the accreditation standards and equivalency is sustained.

In the interest of furthering the mutual goal of promoting quality testing in clinical laboratories and furthering the goal of sustained equivalency, CMS hosts an annual meeting of all CMS-approved AOs for CLIA. The group meets to discuss and resolve issues of mutual interest and to share best practices. The group endeavors to improve their overall consistency in application of laboratory standards, coordination, collaboration, and communication in both routine and emergent situations. Through these efforts we hope to further improve the level of laboratory oversight and ultimately, patient care.

## APPENDIX A: Performance Measures

**Table 1**  
**Performance Measure Results (Percentage) for by Accrediting Organization**  
**Comparable Measures for Fiscal Years 2014-2015**

	AAAASF		AAAHC		ACHC		AOA/HFAP		CHAP		CIHQ		DNV GL		TCT		TJC	
	FY14	FY15	FY14	FY15	FY14	FY15	FY14	FY15	FY14	FY15	FY14	FY15	FY14	FY15	FY14	FY15	FY14	FY15
<b>ASSURE Database</b>																		
Number of CCNs present (not missing >180 days)	100	100	96	95	100	100	100	100	99	98	100	100	100	100	*NA	100	96	96
Timely triennial surveys	100	100	100	99	100	100	100	100	100	100	*NA	*NA	99	99	*NA	*NA	99	99
Denied initial surveys with condition-level findings	0	66	**NA	100	97	100	**NA	100	81	100	**NA	100	**NA	17	*NA	67	0	83
Timely uploading of Web-ASSURE import files	92	100	100	92	100	100	100	100	NA	NA	NA	NA	NA	NA	*NA	NA	100	100
Timely electronic submission of no-match data follow-up	75	100	100	75	100	100	100	100	100	100	*NA	*NA	100	100	*NA	100	100	100
Evidence of no-match reconciliation	100	100	100	100	100	100	100	100	100	100	*NA	*NA	100	100	*NA	100	100	100
<b>Facility Notification Letters</b>																		
Letters submitted with attachments	66	100	100	100	100	100	100	100	91	100	100	100	96	100	*NA	100	86	100

	AAAASF		AAAHC		ACHC		AOA/HFAP		CHAP		CIHQ		DNV GL		TCT		TJC	
	FY14	FY15																
No duplicate notices submitted	100	100	98	100	100	100	100	100	100	100	100	100	100	100	*NA	100	100	100
Notification letters contain all required information	NA <sup>†</sup>	95	NA <sup>†</sup>	88	NA <sup>†</sup>	100	NA <sup>†</sup>	97	NA <sup>†</sup>	99	NA <sup>†</sup>	100	NA <sup>†</sup>	99	NA <sup>†</sup>	92	NA <sup>†</sup>	98
ASSURE is updated consistent with letters	NA <sup>†</sup>	80	NA <sup>†</sup>	90	NA <sup>†</sup>	98	NA <sup>†</sup>	97	NA <sup>†</sup>	76	NA <sup>†</sup>	96	NA <sup>†</sup>	86	NA <sup>†</sup>	82	NA <sup>†</sup>	79
<b>Survey Schedule</b>																		
AO conducted survey as reported on survey schedule	100	100	100	100	100	100	100	100	100	100	100	100	100	100	*NA	100	100	100
Timely submission of schedule changes and proper incorporation into the next monthly schedule	100	100	100	100	100	100	100	100	92	100	100	100	100	100	*NA	100	100	100
Number of surveys performed matches number reported in ASSURE	94	97	82	84	93	100	100	100	94	99	85	100	99	99	*NA	87	97	98
<b>Formal Correspondence</b>																		
Responses to CMS on or before specified due date	100	100	100	100	100	100	100	100	75	100	100	100	42	100	*NA	100	94	100

NA: Data is manually entered into ASSURE

NA<sup>†</sup>: New measure for FY 2015; not reported in FY 2014

\*NA: No information available for calculation

\*\*NA: Not applicable due to sample size less than five

## APPENDIX B: Baseline Analysis – Life Safety Code and Health & Safety Disparity Rates

### Accrediting Organizations

#### American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF)

##### Ambulatory Surgery Centers (ASCs)

AAAASF (FY 2015 ASC Surveys)	All CoPs	PE	Health & Safety
Number of 60 Day Validation Surveys	8	8	8
Number of Surveys with Conditions Missed by AO	3	1	3
Disparity Rate	37.50%	12.50%	37.50%

**Table 1: American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF)  
Ambulatory Surgery Center (ASC) Disparity Rate  
Fiscal Year (FY) 2015**

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Governing Body and Management	2	0	2	25.00%
Infection Control	2	1	1	12.50%
Pharmaceutical Services	1	0	1	12.50%
Medical Staff	1	0	1	12.50%
Environment	1	0	1	12.50%

**Table 2: American Association for Accreditation of Ambulatory Surgery Facilities, Inc.  
Top Five Disparate Conditions of Participation (CoPs) for Ambulatory Surgery Centers  
100% of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Sprinkler	4	4	30.77%
EES	3	3	23.08%
Electrical	2	2	15.38%
Hazardous Areas	2	2	15.38%
Fire Alarm	1	1	7.69%
HVAC	1	1	7.69%
Anesthetizing Location	0	0	0.00%
Construction	0	0	0.00%
Cooking Facility	0	0	0.00%
Doors	0	0	0.00%

**Table 3: American Association for Accreditation of Ambulatory Surgery Facilities, Inc.  
Top 10 Missed Life Safety Code Citations for Ambulatory Surgery Centers  
100% of all Missed Citations**

## Accreditation Association for Ambulatory Health Care, Inc. (AAAHC)

### Ambulatory Surgery Centers (ASCs)

AAAHC (FY 2015 ASC Surveys)	All CoPs	PE	Health & Safety
Number of 60 Day Validation Surveys	42	42	42
Number of Surveys with Conditions Missed by AO	16	8	12
Disparity Rate	<b>38.10%</b>	<b>19.05%</b>	<b>28.57%</b>

**Table 4: Accreditation Association for Ambulatory Health Care, Inc. (AAAHC)  
Ambulatory Surgery Center (ASC) Disparity Rate  
Fiscal Year (FY) 2015**

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Infection Control	10	2	8	19.00%
Environment	9	1	8	19.00%
Governing Body and Management	9	2	7	16.70%
Laboratory and Radiologic services	3	0	3	7.10%
Pharmaceutical Services	3	0	3	7.10%

**Table 5: Accreditation Association for Ambulatory Health Care, Inc.  
Top Five Disparate Conditions of Participation (CoPs) for Ambulatory Surgery Centers  
74% of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Hazardous Areas	16	14	15.73%
Means of Egress	10	6	6.74%
Fire/Smoke Barrier	15	4	4.49%
Emergency Lighting	4	3	3.37%
Fire Plan	5	2	2.25%
Fire Drill	3	2	2.25%
Smoking Regulations	1	1	1.12%

**Table 6: Accreditation Association for Ambulatory Health Care, Inc.  
Missed Life Safety Code Citations for Ambulatory Surgery Centers  
100% of all Missed Citations**

## Accreditation Commission for Health Care (ACHC)

### Home Health Agency (HHA)

ACHC (FY 2015 HHA Surveys)	All CoPs	Health & Safety
Number of 60 Day Validation Surveys	16	16
Number of Surveys with Conditions Missed by AO	2	2
Disparity Rate	<b>12.50%</b>	<b>12.50%</b>

**Table 7: Accreditation Commission for Health Care (ACHC)  
Home Health Agency (HHA) Disparity Rate  
Fiscal Year (FY) 2015**

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Comprehensive Assessment of Patients	2	1	1	6.30%
Evaluation of the Agency's Program	2	1	1	6.30%
Acceptance of Patients, POC, Med Super	2	1	1	6.30%
Group of Professional Personnel	1	0	1	6.30%
Organization, Services & Administration	2	1	1	6.30%

**Table 8: Accreditation Commission for Health Care  
Top Five Disparate Conditions of Participation (CoPs) for Home Health Agencies  
100% of all Disparate Surveys**

### American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)

#### Hospitals

AOA/HFAP (FY 2015 Hospital Surveys)	All CoPs	PE	Health & Safety
Number of 60 Day Validation Surveys	4	4	4
Number of Surveys with Conditions Missed by AO	3	3	NA
Disparity Rate	75.00%	75.00%	NA

**Table 9: American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)  
Hospital Disparity Rate  
Fiscal Year (FY) 2015**

CoP	Facilities with CoP	Matching Surveys	Disparate Surveys	Disparity Rate
PE	4	0	3	75.00%

**Table 10: American Osteopathic Association/Healthcare Facilities Accreditation Program  
Disparate Condition of Participation (CoP) for Hospitals  
100% of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Generator	6	6	13.95%
Anesthetizing Location	2	2	4.65%
Flammable & Combustible Storage	2	2	4.65%
Means of Egress	8	2	4.65%
Emergency Lighting	1	1	2.33%
Fire Drill	1	1	2.33%
Sprinkler	5	1	2.33%

**Table 11: American Osteopathic Association/Healthcare Facilities Accreditation Program  
Missed Life Safety Code Citations for Hospitals  
100% of all Missed Citations**

## Ambulatory Surgery Centers (ASCs)

<b>AOA/HFAP (FY 2015 ASC Surveys)</b>	<b>All CoPs</b>	<b>PE</b>	<b>Health &amp; Safety</b>
Number of 60 Day Validation Surveys	1	1	1
Number of Surveys with Conditions Missed by AO	0	NA	0
Disparity Rate	<b>0.00%</b>	<b>NA</b>	<b>0.00%</b>

**Table 12: American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)  
Ambulatory Surgery Center (ASC) Disparity Rate  
Fiscal Year (FY) 2015**

## Critical Access Hospitals (CAHs)

<b>AOA/HFAP (FY 2015 CAH Surveys)</b>	<b>All CoPs</b>	<b>PE</b>	<b>Health &amp; Safety</b>
Number of 60 Day Validation Surveys	3	3	3
Number of Surveys with Conditions Missed by AO	2	NA	2
Disparity Rate	<b>66.67%</b>	<b>NA</b>	<b>66.67%</b>

**Table 13: American Osteopathic Association/Healthcare Facilities Accreditation Program  
Critical Access Hospital (CAH) Disparity Rate  
Fiscal Year (FY) 2015**

## Community Health Accreditation Partner (CHAP)

### Home Health Agency (HHA)

<b>CHAP (FY 2015 HHA Surveys)</b>	<b>All CoPs</b>	<b>Health &amp; Safety</b>
Number of 60 Day Validation Surveys	51	51
Number of Surveys with Conditions Missed by AO	8	8
Disparity Rate	<b>15.69%</b>	<b>15.69%</b>

**Table 14: Community Health Accreditation Partner (CHAP)  
Home Health Agency (HHA) Disparity Rate  
Fiscal Year (FY) 2015**

<b>CoPs</b>	<b>Facilities with CoPs</b>	<b>Matching Surveys</b>	<b>Disparate Surveys</b>	<b>Disparity Rate</b>
Acceptance of Patients, POC, Med Super	8	3	5	9.80%
Skilled Nursing Service	5	1	4	7.80%
Comprehensive Assessment of Patients	5	2	3	5.90%
Home Health Aide Services	4	1	3	5.90%
Evaluation of the Agency's Program	2	0	2	3.90%

**Table 15: Community Health Accreditation Partner  
Top Five Disparate Conditions of Participation (CoPs) for Home Health Agencies  
77% of all Disparate Surveys**

## Hospice

CHAP (FY 2015 Hospice Surveys)	All CoPs	Health & Safety
Number of 60 Day Validation Surveys	19	19
Number of Surveys with Conditions Missed by AO	1	1
Disparity Rate	5.26%	5.26%

**Table 16: Community Health Accreditation Partner  
Hospice Disparity Rate  
Fiscal Year (FY) 2015**

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
IDG, Care Planning, Coordination of Services	2	1	1	5.30%
Initial & Comprehensive Assessment of Patient	1	0	1	5.30%

**Table 17: Community Health Accreditation Partner  
Disparate Conditions of Participation (CoPs) for Hospice  
100% of all Disparate Surveys**

## Center for Improvement in Healthcare Quality (CIHQ)

### Hospitals

CIHQ (FY 2015 Hospital Surveys)	All CoPs	PE	Health & Safety
Number of 60 Day Validation Surveys	1	1	1
Number of Surveys with Conditions Missed by AO	1	NA	1
Disparity Rate	100.00%	NA	100.00%

**Table 18: Center for Improvement in Healthcare Quality (CIHQ)  
Hospital Disparity Rate  
Fiscal Year (FY) 2015**

CoP	Facilities with CoP	Matching Surveys	Disparate Surveys	Disparity Rate
QAPI	1	0	1	100.00%

**Table 19: Center for Improvement in Healthcare Quality  
Disparate Condition of Participation (CoP) for Hospitals  
100% of all Disparate Surveys**

## DNV GL-Healthcare (DNV GL)

### Hospitals

DNV GL (FY 2015 Hospital Surveys)	All CoPs	PE	Health & Safety
Number of 60 Day Validation Surveys	8	8	8
Number of Surveys with Conditions Missed by AO	4	2	2
Disparity Rate	50.00%	25.00%	25.00%

**Table 20: DNV GL-Healthcare (DNV GL)  
Hospital Disparity Rate  
Fiscal Year (FY) 2015**

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
PE	2	0	2	25.00%
Infection Control	2	1	1	12.50%
Respiratory Care Services	1	0	1	12.50%

**Table 21: DNV GL-Healthcare  
Disparate Conditions of Participation (CoPs) for Hospitals  
100% of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Means of Egress	14	14	19.18%
Hazardous Areas	9	9	12.33%
Fire/Smoke Barrier	6	6	8.22%
Sprinkler	9	6	8.22%
Construction	5	5	6.85%
Fire Alarm	5	4	5.48%
HVAC	5	4	5.48%
Generator	3	3	4.11%
Doors	6	2	2.74%
Medical Gas	4	2	2.74%

**Table 22: DNV GL-Healthcare  
Top 10 Missed Life Safety Code Citations for Hospitals  
93% of all Missed Citations**

### Critical Access Hospitals (CAHs)

DNV GL (FY 2015 CAHs)	All CoPs	PE	Health & Safety
Number of 60 Day Validation Surveys	2	2	2
Number of Surveys with Conditions Missed by AO	2	2	NA
Disparity Rate	100.00%	100.00%	NA

**Table 23: DNV GL-Healthcare (DNV GL)  
Critical Access Hospitals (CAHs) Disparity Rate  
Fiscal Year (FY) 2015**

CoP	Facilities with CoP	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Plant and Environment	2	0	2	100.00%

**Table 24: DNV GL-Healthcare  
Disparate Condition of Participation (CoP) for Critical Access Hospitals  
100% of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Means of Egress	10	7	21.21%
Fire/Smoke Barrier	5	4	12.12%
Electrical	4	3	9.09%
EES	2	2	6.06%
Fire Alarm	2	2	6.06%
Sprinkler	4	2	6.06%
Doors	3	1	3.03%
Emergency Lighting	1	1	3.03%

**Table 25: DNV GL-Healthcare  
Missed Life Safety Code Citations for Critical Access Hospitals  
100% of all Missed Citations**

### The Joint Commission (TJC)

#### Hospitals

TJC (FY 2015 Hospital and LTCH Surveys)	All CoPs	PE	Health & Safety
Number of 60 Day Validation Surveys	89	89	89
Number of Surveys with Conditions Missed by AO	32	22	13
Disparity Rate	35.96 %	24.72%	14.61%

**Table 26: The Joint Commission (TJC)  
Hospital and Long Term Care Hospital (LTCH) Disparity Rate  
Fiscal Year (FY) 2015**

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
PE	22	0	22	24.70%
Infection Control	7	1	6	6.70%
Governing Body	8	2	6	6.70%
Patient Rights	7	3	4	4.50%
Food and Dietetic Services	3	0	3	3.40%

**Table 27: The Joint Commission  
Top Five Disparate Conditions of Participation (CoPs) for Hospitals  
85% of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Sprinkler	70	56	11.89%
Means of Egress	65	47	9.98%
Fire/Smoke Barrier	62	38	8.07%
Hazardous Areas	58	34	7.22%
Electrical	47	29	6.16%
Doors	38	27	5.73%
Fire Alarm	24	14	2.97%
Fire Extinguisher	14	11	2.34%
EES	8	8	1.70%
HVAC	11	8	1.70%

**Table 28: The Joint Commission  
Top 10 Missed Life Safety Code Citations for Hospital  
89% of all Missed Citations**

### Psychiatric Hospitals

TJC (FY 2015 Psychiatric Hospital Surveys)	All CoPs	PE	Health & Safety
Number of 60 Day Validation Surveys	16	16	16
Number of Surveys with Conditions Missed by AO	11	6	10
Disparity Rate	68.75%	37.50%	62.50%

**Table 29: The Joint Commission (TJC)  
Psychiatric Hospital Disparity Rate  
Fiscal Year (FY) 2015**

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Special Medical Record Reqs for Psych Hospitals	14	5	9	56.30%
PE	6	0	6	37.50%
QAPI	5	1	4	25.00%
Special Staff Reqs for Psych Hospitals	3	0	3	18.80%
Infection Control	3	1	2	12.50%

**Table 30: The Joint Commission  
Top Five Disparate Conditions of Participation (CoPs) for Psychiatric Hospitals  
65% of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Doors	8	7	8.05%
Fire/Smoke Barrier	18	7	8.05%
Sprinkler	9	5	5.75%
Construction	4	4	4.60%
Means of Egress	8	3	3.45%
Cooking Facility	2	2	2.30%
Electrical	7	2	2.30%
Hazardous Areas	12	2	2.30%
Fire Drill	2	1	1.15%
Fire Extinguisher	1	1	1.15%

**Table 31: The Joint Commission  
Top 10 Missed Life Safety Code Citations for Psychiatric Hospitals  
94% of all Missed Citations**

### Ambulatory Surgery Centers (ASCs)

TJC (FY 2015 ASC Surveys)	All CoPs	PE	Health & Safety
Number of 60 Day Validation Surveys	18	18	18
Number of Surveys with Conditions Missed by AO	10	3	8
Disparity Rate	<b>55.56%</b>	<b>16.67%</b>	<b>44.44%</b>

**Table 32: The Joint Commission (TJC)  
Ambulatory Surgery Center (ASC) Disparity Rate  
Fiscal Year (FY) 2015**

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Infection Control	10	4	6	33.30%
Governing Body and Management	9	3	6	33.30%
Environment	3	0	3	16.70%
Pharmaceutical Services	3	1	2	11.10%
Quality Assessment & Performance Improvement	3	1	2	11.10%

**Table 33: The Joint Commission  
Top Five Disparate Conditions of Participation (CoPs) for Ambulatory Surgery Centers  
73% of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Medical Gas	8	6	17.14%
Fire Alarm	6	5	14.29%
Fire/Smoke Barrier	7	5	14.29%
Sprinkler	5	5	14.29%
Anesthetizing Location	1	1	2.86%
Construction	1	1	2.86%
Electrical	1	1	2.86%
Emergency Lighting	1	1	2.86%
Generator	2	1	2.86%
Means of Egress	1	1	2.86%

**Table 34: The Joint Commission  
Top 10 Missed Life Safety Code Citations for Ambulatory Surgery Centers  
100% of all Missed Citations**

### Home Health Agency (HHA)

TJC (FY 2015 HHA Surveys)	All CoPs	Health & Safety
Number of 60 Day Validation Surveys	37	37
Number of Surveys with Conditions Missed by AO	7	7
Disparity Rate	18.92%	18.92%

**Table 35: The Joint Commission (TJC)  
Home Health Agency (HHA) Disparity Rate  
Fiscal Year (FY) 2015**

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Organization, Services & Administration	4	1	3	8.10%
Clinical Records	3	1	2	5.40%
Home Health Aide Services	4	2	2	5.40%
Acceptance of Patients, POC, Med Super	5	3	2	5.40%
Evaluation of the Agency's Program	5	4	1	2.70%

**Table 36: The Joint Commission  
Top Five Disparate Conditions of Participation (CoPs) for Home Health Agencies  
77% of all Disparate Surveys**

### Hospice

TJC (FY 2015 Hospice Surveys)	All CoPs	Health & Safety
Number of 60 Day Validation Surveys	10	10
Number of Surveys with Conditions Missed by AO	2	2
Disparity Rate	20.00%	20.00%

**Table 37: The Joint Commission (TJC)  
Hospice Disparity Rate  
Fiscal Year (FY) 2015**

CoPs	Facilities with CoP	Matching Surveys	Disparate Surveys	Disparity Rate
Hospices that provide inpatient care directly	1	0	1	10.00%
Residents of SNF/NF or ICF/MR	1	0	1	10.00%

**Table 38: The Joint Commission Disparate Conditions of Participation (CoPs) for Hospice  
100% of all Disparate Surveys**

### Critical Access Hospitals (CAHs)

TJC (FY 2015 CAH Surveys)	All CoPs	PE	Health & Safety
Number of 60 Day Validation Surveys	28	28	28
Number of Surveys with Conditions Missed by AO	11	6	7
Disparity Rate	<b>39.29%</b>	<b>21.43%</b>	<b>25.00%</b>

**Table 39: The Joint Commission (TJC)  
Critical Access Hospital (CAH) Disparity Rate  
Fiscal Year (FY) 2015**

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Plant and Environment	8	2	6	21.40%
Provision of Services	6	2	4	14.30%
Surgical Services	5	2	3	10.70%
Special Reqs for CAH Providers of LTC Srvcs	2	0	2	7.10%
Organizational Structure	2	0	2	7.10%

**Table 40: The Joint Commission  
Top Five Disparate Conditions of Participation (CoPs) for Critical Access Hospitals  
81% of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Hazardous Areas	15	15	18.07%
Fire/Smoke Barrier	12	9	10.84%
Sprinkler	11	9	10.84%
Doors	8	6	7.23%
Anesthetizing Location	4	4	4.82%
Construction	1	1	1.20%
EES	2	1	1.20%
Flammable & Combustible Storage	1	1	1.20%
Furnishings & Decorations	1	1	1.20%

**Table 41: The Joint Commission  
Missed Life Safety Code Citations for Critical Access Hospitals  
100% of all Missed Citations**

## Program Types

### Hospitals

<b>ALL AOs (FY 2014 Hospital and LTCH Surveys)</b>	<b>All CoPs</b>	<b>PE</b>	<b>Health &amp; Safety</b>
Number of 60 Day Validation Surveys	102	102	102
Number of Surveys with Conditions Missed by AO	40	27	16
<b>Disparity Rate</b>	<b>39.22 %</b>	<b>26.47%</b>	<b>15.69%</b>

**Table 42: Hospital Disparities**

<b>CoPs</b>	<b>Facilities with CoPs</b>	<b>Matching Surveys</b>	<b>Disparate Surveys</b>	<b>Disparity Rate</b>
PE	27	0	27	26.50%
Infection Control	10	3	7	6.90%
Governing Body	8	2	6	5.90%
Patient Rights	7	3	4	3.90%
Food and Dietetic Services	3	0	3	2.90%

**Table 43: Top Five Disparate CoPs for Hospitals**  
**84% of all Disparate Surveys**

<b>Category</b>	<b>Total Cited by SA</b>	<b>Missed by AO</b>	<b>Disparity Rate</b>
Means of Egress	87	63	10.73%
Sprinkler	84	63	10.73%
Fire/Smoke Barrier	73	42	7.16%
Hazardous Areas	72	41	6.98%
Doors	46	28	4.77%
Electrical	50	24	4.09%
Fire Alarm	29	16	2.73%
Generator	22	16	2.73%
HVAC	17	12	2.04%
Fire Extinguisher	14	11	1.87%

**Table 44: Top 10 Missed Life Safety Code Citations for Hospitals**  
**88% of all Missed Citations**

### Psychiatric Hospitals

<b>ALL AOs (FY 2014 Psychiatric Hospital Surveys)</b>	<b>All CoPs</b>	<b>PE</b>	<b>Health &amp; Safety</b>
Number of 60 Day Validation Surveys	16	16	16
Number of Surveys with Conditions Missed by AO	11	6	10
<b>Disparity Rate</b>	<b>68.75%</b>	<b>37.50%</b>	<b>62.50%</b>

**Table 45: Psychiatric Hospital Disparities**

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Special Medical Record Reqs for Psych Hospitals	14	5	9	56.30%
PE	6	0	6	37.50%
QAPI	5	1	4	25.00%
Special Staff Reqs for Psych Hospitals	3	0	3	18.80%
Infection Control	3	1	2	12.50%

**Table 46: Top Five Disparate Conditions of Participation (CoPs) for Psychiatric Hospitals  
65% of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Doors	8	7	8.05%
Fire/Smoke Barrier	18	7	8.05%
Sprinkler	9	5	5.75%
Construction	4	4	4.60%
Means of Egress	8	3	3.45%
Cooking Facility	2	2	2.30%
Electrical	7	2	2.30%
Hazardous Areas	12	2	2.30%
Fire Drill	2	1	1.15%
Fire Extinguisher	1	1	1.15%

**Table 47: Top 10 Missed Life Safety Code Citations for Psychiatric Hospitals  
94% of all Missed Citations**

### Ambulatory Surgery Centers (ASCs)

ALL AOs (FY 2014 ASC Surveys)	All CoPs	PE	Health & Safety
Number of 60 Day Validation Surveys	69	69	69
Number of Surveys with Conditions Missed by AO	29	12	23
<b>Disparity Rate</b>	<b>42.03%</b>	<b>17.39%</b>	<b>33.33%</b>

**Table 48: Ambulatory Surgery Center (ASC) Disparities**

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Infection Control	23	8	15	21.70%
Governing Body and Management	21	6	15	21.70%
Environment	13	1	12	17.40%
Pharmaceutical Services	7	1	6	8.70%
Laboratory and Radiologic Services	4	0	4	5.80%

**Table 49: Top Five Disparate Conditions of Participation (CoPs) for Ambulatory Surgery Centers  
73% of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Hazardous Areas	18	16	11.68%
Fire/Smoke Barrier	22	9	6.57%
Means of Egress	11	7	5.11%
Emergency Lighting	5	4	2.92%
Medical Gas	14	4	2.92%
Fire Drill	4	2	1.46%
Construction	1	1	0.73%
Electrical	9	1	0.73%
Fire Plan	5	1	0.73%
HVAC	5	1	0.73%

**Table 50: Top 10 Missed Life Safety Code Citations for Ambulatory Surgery Centers  
96% of all Missed Citations**

### Critical Access Hospitals (CAHs)

ALL AOs (FY 2014 CAH Surveys)	All CoPs	PE	Health & Safety
Number of 60 Day Validation Surveys	33	33	33
Number of Surveys with Conditions Missed by AO	15	8	9
<b>Disparity Rate</b>	<b>45.45%</b>	<b>24.24%</b>	<b>27.27%</b>

**Table 51: Critical Access Hospital (CAH) Disparities**

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Plant and Environment	10	2	8	24.20%
Provision of Services	7	2	5	15.20%
Surgical Services	5	2	3	9.10%
Special Reqs for CAH Providers of LTC Services	2	0	2	6.10%
Organizational Structure	2	0	2	6.10%

**Table 52: Top Five Disparate Conditions of Participation (CoPs) for Critical Access Hospitals  
73% of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Hazardous Areas	15	15	12.93%
Fire/Smoke Barrier	17	13	11.21%
Sprinkler	15	11	9.48%
Doors	11	7	6.03%
Anesthetizing Location	4	3	2.59%
EES	4	3	2.59%
Means of Egress	16	3	2.59%
Construction	1	1	0.86%
Electrical	9	1	0.86%
Fire Alarm	8	1	0.86%

**Table 53: Top 10 Missed Life Safety Code Citations for Critical Access Hospitals  
96% of all Missed Citations**

## Hospice

<b>ALL AOs (FY 2014 Hospice Surveys)</b>	<b>All CoPs</b>	<b>Health &amp; Safety</b>
Number of 60 Day Validation Surveys	34	34
Number of Surveys with Conditions Missed by AO	3	3
<b>Disparity Rate</b>	<b>8.82%</b>	<b>8.82%</b>

**Table 54: Hospice Disparities**

<b>CoPs</b>	<b>Facilities with CoP(s)</b>	<b>Matching Surveys</b>	<b>Disparate Surveys</b>	<b>Disparity Rate</b>
IDG, Care Planning, Coordination of Services	2	1	1	2.90%
Initial & Comprehensive Assessment of Patient	1	0	1	2.90%
Residents of SNF/NF or ICF/MR	1	0	1	2.90%
Hospices that Provide Inpatient Care Directly	1	0	1	2.90%

**Table 55: Disparate Conditions of Participation (CoPs) for Hospice Facilities  
100% of all Disparate Surveys**

## Home Health Agency (HHA)

<b>ALL AOs (FY 2014 HHA Surveys)</b>	<b>All CoPs</b>	<b>Health &amp; Safety</b>
Number of 60 Day Validation Surveys	104	104
Number of Surveys with Conditions Missed by AO	17	17
<b>Disparity Rate</b>	<b>16.35%</b>	<b>16.35%</b>

**Table 56: Home Health Agency (HHA) Disparities**

<b>CoPs</b>	<b>Facilities with CoPs</b>	<b>Matching Surveys</b>	<b>Disparate Surveys</b>	<b>Disparity Rate</b>
Acceptance of Patients, POC, Med Super	15	7	8	7.70%
Organization, Services & Administration	9	3	6	5.80%
Home Health Aide Services	9	4	5	4.80%
Comprehensive Assessment of Patients	10	6	4	3.80%
Evaluation of the Agency's Program	9	5	4	3.80%

**Table 57: Top Five Disparate Conditions of Participation (CoPs) for Home Health Agencies  
68% of all Disparate Surveys**

## **APPENDIX C: Life Safety Code Definitions as adopted by CMS for use in Facility Accreditation Surveys**

**Anesthetizing Location:** Location where inhalation agents are used to produce sedation, analgesia, or general anesthesia.

**Construction:** Buildings should be classified to their type of construction based on the five different construction types: Type I, Type II, Type III, Type IV, and Type V with fire resistive ratings.

**Cooking Facility:** An area for food preparation and commercial cooking operations requiring protection for exhaust and automatic extinguishing system.

**Doors:** The door assembly including any combination of a door, frame, hardware, and other accessories that is placed in an opening in a wall that is intended primarily for access or for human entrance or exit.

**Electrical:** Electrically connected energized with a source of voltage and general term of equipment, including fitting, devices, appliances, luminaires, apparatus, machinery and the like used as part of electrical installation.

**Elevator:** A machine used for carrying people and things to different levels in a building and components, machinery and shaft.

**Fire Plan:** A fire or emergency management program that is documented that shall include four phases including mitigation, preparedness, response, and recovery.

**Emergency Lighting:** Emergency illumination provided for means of egress in designated areas and the performance of the system in relation to length of operation and testing.

**Essential Electrical System (EES):** A system comprised of alternate sources of power and all connected distribution systems and ancillary equipment, designed to ensure continuity of electrical power to designated areas and functions of a health care facility during interruption of normal power sources, and also to minimize disruption within the internal wiring system.

**Eye Wash:** An apparatus for irrigating the eyes after exposure to dust or other debris or chemical contamination. The shower directs one or two streams of water so that they flush over the eyes and lids and must be inspected and maintained.

**Fire Alarm:** A system or portion of a combination system that consist of components and circuits arranged to monitor and annunciate the status of fire alarm or supervisory signal initiating device to initiate the proper response to those signals.

**Fire Drill:** Practice of the fire plan to evacuate or relocate persons in the event of a fire to be conducted quarterly for each shift.

**Fire extinguisher:** A portable device, carried or on wheels and operated by hand, containing an extinguishing agent that can be expelled under pressure for the purpose of suppressing or extinguishing a fire.

**Fire / Smoke Barrier:** Fire compartment or Smoke compartment within a building enclosed by either a fire or smoke barrier on all sides including the top and bottom.

**Flammable & Combustible Storage:** Storage area for combustible materials that has a flash point at or above a 100° F and flammable materials that has a flash point at or below 100° F.

**Furnishings and Decorations:** Draperies, curtains, and other loosely hanging fabrics and films servicing as furnishings or decorations in health care occupancies.

**Generator:** A complete emergency power system coupled to a system of conductors, disconnecting means and overcurrent protective devices, transfer switches, and all control, supervisory, and support devices up to and including the load terminals of the transfer equipment needed for the system to operate as a safe and reliable source of electrical power.

**Hazardous Areas:** An area of a structure or building that poses a degree of hazard greater than that normal to the general occupancy of the building or structure.

**Heating Venting Air Conditioning (HVAC):** System components and air distribution; integration of ventilation of air conditioning system with building construction, including air handling rooms, protection of openings, and fire, smoke, and ceiling dampers; and automatic controls and acceptance testing.

**Interior Finish:** The exposed surfaces of walls, ceilings, and floors in a building.

**Means of Egress:** A continuous and unobstructed way of travel from any point in a building or structure to a public way consisting of three separate and distinct parts: (1) the exit access, (2) the exit, and (3) the exit discharge.

**Medical Gas:** A patient medical gas or support gas. An assembly of equipment and piping for the distribution of nonflammable medical gases such as oxygen, nitrous oxide, compressed air, carbon dioxide, and helium.

**Smoking Regulations:** Regulations adopted pertaining to locations prohibited, signs, and containers permitted for disposal.

**Sprinkler:** A system that consist of an integrated network of piping designed in accordance with fire protection engineering standards that includes a water supply source, a water control valve, a water flow alarm, and a drain. The system is normally activated from a fire and discharges water over the fire area through sprinkler heads.